R2™ DM

User Manual

Software Version 8.5

PN MAN-00709 Rev 001

HOLOGIC® | R2 Earlier. Smarter. Better.™

Mammography

R2™ DM User Manual

Software Version 8.5

PN MAN-00709 Rev 001

HOLOGIC® | R2 Earlier. Smarter. Better.™

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MergeCOM-3 Advanced Integrator's Tool Kit is a product of Merge Healthcare.

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Part 1: Introduction

- 1.1. Available Resources
- 1.2. How to Use this Manual
- 1.3. Warnings and Cautions

Part 1 provides a brief description of resources available from Hologic | R2, information about using this manual, and safety information.

1.1. Available Resources

When you are working with the R2 DM system, the following resources are available from Hologic | R2:

- **Onscreen Messages:** The R2 GreenLight™ user interface is designed to guide you as you use the system. Onscreen messages appear when appropriate and provide friendly instructions.
- **Technical Support and Service:** For contact information, see 'Technical Support' on the back of the title page of this manual.
- **User Manuals:** This user manual describes the use of the R2 DM system and provides maintenance and troubleshooting instructions in a simple, streamlined format. You can purchase additional copies of the user manual through your Hologic | R2 Account Manager.
- **Customer Bulletins:** Hologic | R2 is committed to making our products safe and easy to use. If an issue arises or new features become available, you will receive a Customer Bulletin.
- **Training:** On-line training materials are available through the R2 Member Center, which is available at http://www.r2tech.com/main/member_login.php. Simply register for access to a wide range of training courses on v8.5 software. In addition, the Hologic | R2 Applications team is available to train your staff, should you feel they need additional training. Contact your Hologic | R2 Account Manager if you want personalized instruction.

1.2. How to Use this Manual

This manual was written to ensure safe and proper use of the system. Before use, read this manual carefully in order to realize the full capabilities of the system. If something is unclear during daily use or if a problem occurs, please refer to this manual.

Manual Organization

This manual is organized as follows:

- **Part 1: Introduction** provides a list of resources available from Hologic | R2, information about using this manual, and safety information.
- **Part 2: Description** provides background information on the system, component and feature descriptions, an overview of operation, and CAD processing information.
- **Part 3: Studies** provides instructions for working with films, scanning them, displaying study results, verifying and labeling images, and searching for a study.
- **Part 4: Alerts** provides a listing of alert conditions with instructions for resolving the alerts and diagnosing and solving common problems.
- **Part 5: Controls** provides instructions for using the system configuration and maintenance options that appear on the Controls screen.
- **Part 6: Maintenance** provides instructions for cleaning the system and running the weekly tests.
- **Part 7: Using DigitalNow and the R2 Patient ID System** provides information about archiving images with the R2 DigitalNow™ feature and the R2 Patient ID system.

Conventions Used in this Manual

This manual uses the following conventions to provide technical and safety information of special interest.

⚠ ***Note:*** *Background information provided to clarify a particular step or procedure.*

⚠ ***Important:*** *An instruction provided to ensure correct results and optimal performance.*

⚠ ***Caution:*** *An instruction that, if not followed, can result in damage to the system.*

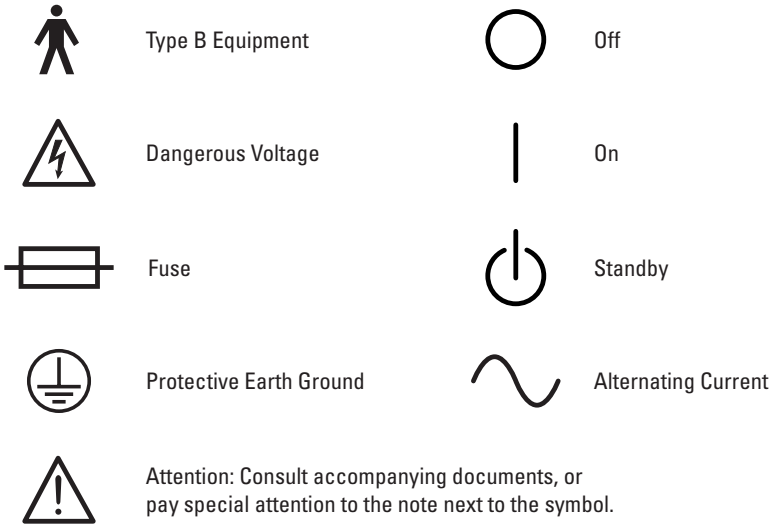
⚠ ***WARNING!*** *An instruction that, if not followed, can result in a hazardous condition.*

Also note the following conventions:

- *Italic* and **boldface** typefaces are used for emphasis. Examples: 'Press *carefully* to engage,' '**Do not** press down.'
- When this manual directs you to touch a button on the touch-screen monitor, the name of the button is shown in boldface type; for example, 'Touch **Start**'.
- When this manual directs you to press a key on the computer keyboard, the key names are outlined; for example, 'Press ↵Enter'.
- If you are reading this manual online, click on the blue hyperlinked text to jump to the referenced section.

Symbols Used

The following internationally recognized symbols may be used in this manual and on R2 products.



Common Symbols

1.3. Warnings and Cautions

Radiological Interpretation

- The radiologist should base interpretation only on the original images and not depend on the CAD marks for interpretation.
- The device is a detection aid, not an interpretative aid. Activate the CAD marks only after the first reading.
- The device marks calcification features with triangles (Calc marks) and mass features with asterisks (Mass marks). Where mass and calcification features overlap within a specified distance (10-mm default), the device marks overlapping features with pointed crosses (Malc™ marks). These features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- EmphaSize (variable-size) marks – Sites may choose to display prominence detail, in which case the size of a Calc, Mass, or Malc mark is proportional to the ranking of the feature by the algorithm. The marked features may not represent cancer, and the skill of the user is still required for proper interpretation of areas marked by the device.
- For proper system operation, the technical quality of the original films or images (e.g., contrast) should meet relevant MQSA standards (or the appropriate national standards) and be acceptable to the mammographer.
- The use of digitized images (scanned film images) for primary reading has not been approved by MQSA. Digitized film images retrieved from archive should be used only for the purpose of comparison with digital images meeting the current standard.
- The device does not identify all areas that are suspicious for cancer.

  – Some lesions are not marked by the device and a user should not be dissuaded from working up a finding if the device fails to mark that site.

  – The device is not designed to detect changes from prior mammograms.

  – The device is not designed to detect skin thickening or nipple retractions.

  – Conditions of the breast that diminish mammographic sensitivity, such as density of normal tissue, also diminish the sensitivity of the device.

  – The device is more sensitive for detection of calcifications than masses, and the sensitivity depends on the site-specific operating points chosen. For sensitivity values, see 'CAD Operating Points' on page 24. In addition to not marking all masses, the algorithm has a lower sensitivity for masses greater than 2.5 cm in diameter.

  – Individual practice patterns may influence results obtained when using this device. Therefore, each facility and radiologist should carefully monitor the results that this device has on their practice of mammography in order to optimize its effectiveness.
- Safety and effectiveness have not been established for analyzing mammograms from patients with breast implants. For patients with breast implants, only

Implant-Displaced Views can be processed by the system and only in cases with a maximum of 2.5 cm (1 in) of the breast implant appearing on the image.

- The performance of the system has not been characterized for special diagnostic views (e.g., magnified views or spot-compressed views). Process only full-view diagnostic images.
- The performance of the system has not been characterized for segmented views of the breast (e.g., 'mosaic' views) where there is not a clear breast border. Process only views with breast borders.

Warnings: System Operation

- Use the system only outside the patient environment. The system is rated for use only in an office environment.
- Remove all potentially obstructive jewelry and clothing before loading films in the processing unit, to minimize the possibility of injury due to moving parts, or damage to the system.
- The symbol next to the power connector indicates a potential shock hazard. Ensure that the system is connected to a power receptacle that is properly grounded and provides voltage and current within the specifications of the system to reduce the likelihood of electrical shock or fire hazard.
- There is a small risk of electrostatic discharge (static electricity). It is mostly a nuisance and not likely to cause harm. However, a shock can cause accidental injury, if, for example, you suddenly withdraw your arm and hit it against something. To minimize possibility of shock, maintain greater than 40% relative humidity, use shoes with natural-material soles, place equipment on nonpolymer floors such as concrete, wood, or floors treated with static dissipative, and/or routinely touch metal with a metal object, such as a key, to painlessly discharge the charge from your body.
- Do not place liquid containers on the device. In the event of a spill, shut down power to all components prior to cleaning to minimize the possibility of electrical shock. Do not operate the device if internal components are exposed to liquid. Contact your service representative.

Warnings: Maintenance

- Barcode scanners used with the system are Class I Laser/LED products – do not stare into the beam.
- Before cleaning the computer, always shut down the system according to the shutdown procedures in this user manual and disconnect the power cord to prevent the possibility of electrical shock. Never use alcohol, benzene, thinner, or other flammable cleaning agents.
- Never use a two-prong plug or extension cord to connect primary power to the system. Use of a two-prong adapter disconnects the utility ground and creates a severe shock hazard.
- The R2 scanners are heavy. It is recommended that two people participate when moving equipment.

Cautions: System Operation

- Operators should review this user manual and receive training before using the system.
- To ensure optimal system performance, perform the system verification tests and scanner maintenance procedures as instructed in this user manual.
- To ensure proper system operation, use only separator sheets and barcodes provided by Hologic | R2.
- To properly identify patients in the archive system, be sure to enter the patient information and the barcode from the separator sheet into the patient identification system correctly.
- For sites with multiple processing systems: When entering data into the R2 Patient ID web page, check the name of the processing unit on the web page to ensure that you are entering the patient information into the processing unit that you will use to scan the case.
- For the display images to correspond correctly to the film position at the display unit, be sure to orient and order the films correctly when scanning, as described in this user manual.
- Ensure that the case retrieved from the archive to be used for comparison is from the same patient as the current case under review. It is recommended that you use the patient flash for this confirmation.
- Use only standard mammographic film: 18 × 24 cm or 24 × 30 cm.
- Do not attempt to scan films that have labels or tape with edges within 1 mm of the edge of the film, or labels that are not pressed flat, or have curled corners, as they may jam.
- Do not attempt to scan bent, damaged, or curled films, as they may jam.
- Always shut down the system according to the procedures provided in this user manual. Failure to shut the system down properly can cause loss of data or damage to the computer operating system.
- This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference, in which case the user will be required to correct the interference at her or his own expense.

⚠ ***Note:*** *The device design and mode of operation are consistent with current standard mammography clinical practices, as governed by the requirements of the Mammography Quality Standards Act (MQSA) of 1992. Users are cautioned to comply with the MQSA or the appropriate national standards, when implementing R2 systems in clinical protocols.*

Cautions: Installation and Maintenance

This product contains no user-serviceable parts. To prevent damage to the system:

- Maintain equipment in a well-ventilated, air-conditioned environment.
- When necessary, shut down the system according to the procedures recommended in this user manual.
- Do not attempt to install or repair the R2 system. Only trained personnel, authorized by Hologic | R2, are qualified to install or repair the system.

For service training, contact your technical service representative or call Hologic | R2 Technical Support (see 'Technical Support' on the back of the title page of this manual).

Part 2: Description

- 2.1. Overview
- 2.2. System Components
- 2.3. Overview of Operation
- 2.4. System Features
- 2.5. ImageChecker Film-Screen CAD
- 2.6. System Inputs and Outputs

Part 2 provides an overview of the system, a description of system components, an overview of system operation and features, and information about CAD processing.

2.1. Overview

The R2 DM system is a full-featured mammography film-scanning platform designed to:

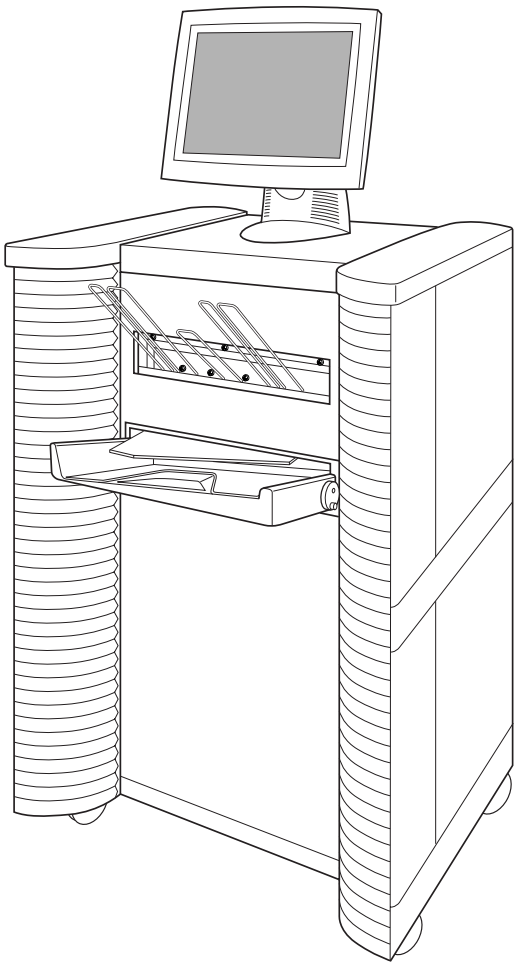
- Scan mammography x-ray films and convert them into digital image files
- Analyze the images using R2 Technology's proprietary ImageChecker® CAD algorithm to detect regions of the breast that may be cancerous
- Allow users to review the scanned images, and to reorient, label, and reprocess the images as needed
- Interface with mammography reporting systems to retrieve patient information, which can then be integrated with the study images
- Transmit the study results to an output device such as an R2 CheckMate™ Ultra display unit or PACS where they can be viewed or archived

⚠ ***Note:*** *This manual uses the following terms to describe mammography images and media:*

- ***Case:*** *a series of x-ray films associated with a particular patient.*
- ***Stack:*** *a group of cases including a separator sheet on top of each case.*
- ***Study:*** *a series of digitized images associated with a particular patient.*

The R2 DM system consists of a touch-screen monitor, a handheld barcode scanner, a keyboard, a film scanner, and a computer that performs the ImageChecker CAD and DigitalNow processing, all housed in a movable cart.

When using the system, the technologist loads a stack of cases into the film scanner. Each case can include from 1 to 24 x-ray mammography films. The technologist inserts a barcoded R2 separator sheet before each case. When the technologist touches the Start button on the touch screen, the system begins scanning the films, converting each film into a digital image, and starting a new case each time it encounters a separator sheet. After each case is scanned, the technologist has the option to review the case and verify that the films were scanned correctly. Then the system sends the images or CAD results to output devices such as display units, PACS or softcopy review workstations.



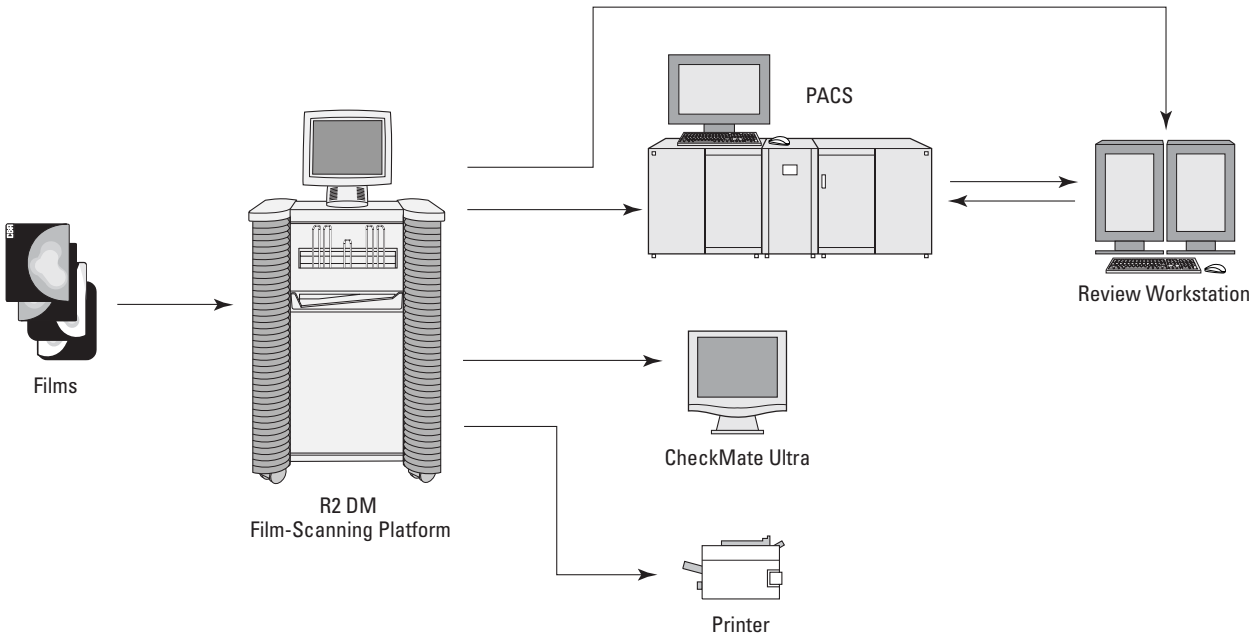
R2 DM System

If the system is configured with the ImageChecker CAD license, it analyzes the scanned images with a proprietary algorithm (i.e., a set of criteria) that identifies regions of interest, which can include clusters of bright spots (suggestive of calcification clusters), and dense regions with or without radiating lines (suggestive of masses or architectural distortions). The system generates CAD marks identifying the regions of interest. Images with CAD results can be sent to an R2 display unit, PACS, review workstation, or printer.

After making an initial interpretation from the original mammograms, the radiologist displays the CAD marks and chooses whether or not to reinspect the marked regions on the original mammogram. The ImageChecker algorithm marks visually perceptible structures that have some of the generally accepted geometric characteristics of calcifications or masses. The marked areas may be something other than an actual abnormality, which is generally recognized by the radiologist upon a second review of the original mammogram.

R2 software version 8.5 now includes the ability to send images and/or CAD results to virtually any DICOM-conformant workstation and/or archive (using R2 Technology's DigitalNow feature), allowing CAD results to be displayed, stored, and managed universally.

For more information about the CAD marks and the ImageChecker algorithm, see '2.5. ImageChecker Film-Screen CAD'.

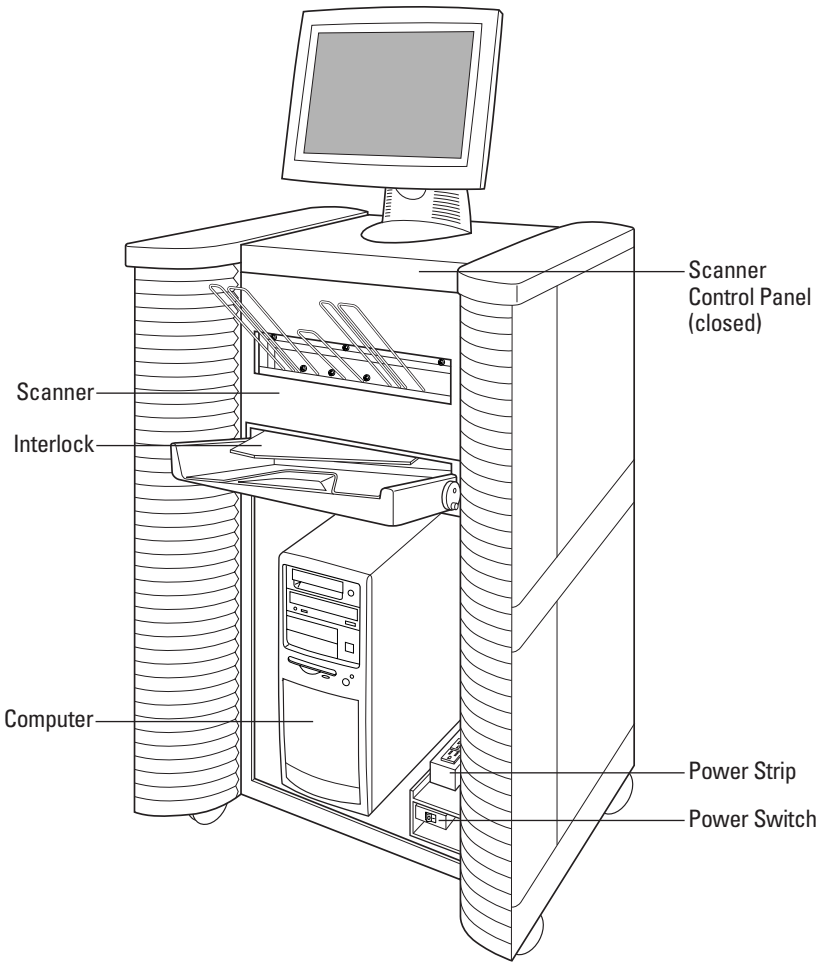


System Diagram

2.2. System Components

This section describes the major system components.

- **Touch-Screen Monitor**: Use to control and monitor the system (start scanning, select studies, view system status, etc.).
- **Scanner**: Use to convert the mammogram films to digital images. You stack the films and place them in the input tray. After the scanner digitizes the images, it stacks the films in the output tray. The DM system scans each film in about 60 seconds.
- **Barcode Scanner**: Use to select a study to display by scanning a barcoded patient ID or the barcode on a separator sheet.
- **Keyboard**: Use to type search criteria when searching for studies, and to enter patient information.
- **Mouse**: Use to select screen objects as an alternative to the touch screen.

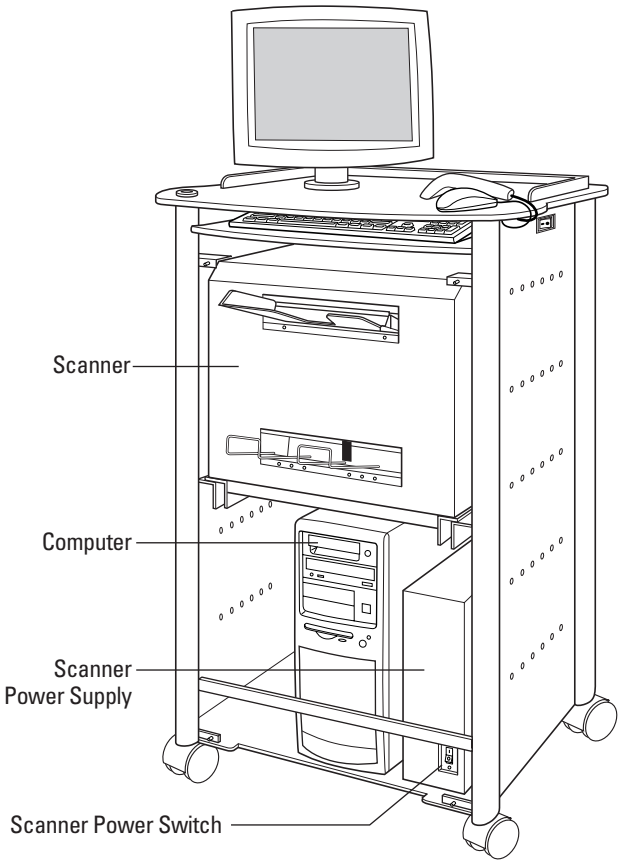


Exterior Components

- **Separator Sheets**: The separator sheet provides a unique R2 ID number (a 10-digit barcode) that the system reads and uses to identify each case and associate the scanned images with the patient's films. Each case fed into the R2 system has its own separator sheet.
- **Test Sheets and Films**: Use for the weekly tests to ensure optimal system performance. For more information, see '6.4. Running the Weekly Tests'.
- **Lead Markers:** Read by the R2 system to identify standard views automatically. For more information on lead markers, see 'R2-Supported Lead Markers' on page 30.

The following components are located behind the front cover. You'll only need to access these components for certain maintenance procedures.

- **Computer:** Processes the scanned films and images.
- **Scanner Power Supply:** Provides power to the scanner.



Interior Components

2.3. Overview of Operation

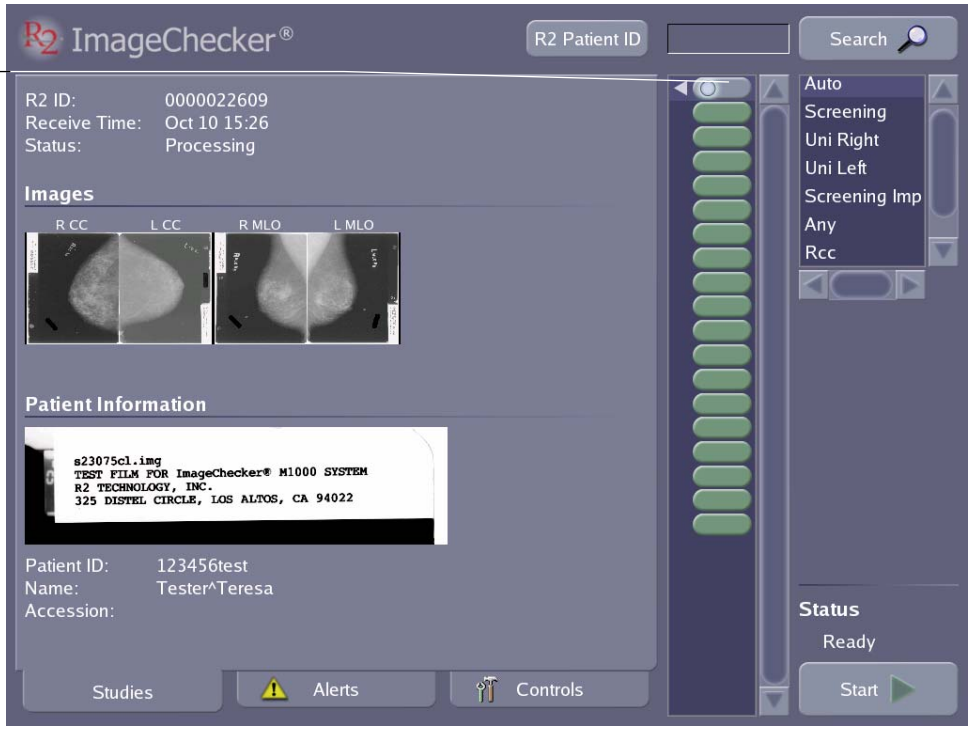
The system's touch-screen interface provides quick access to all system functions. The GreenLight user interface features three main screens – **Studies**, **Alerts**, and **Controls** – plus a common area with film scanning and search options at the right. You can go to each screen by touching one of the tabs at the bottom of the display.

Studies Screen Overview

When scanning films, you will use the **Studies** screen, which is shown below:

The Study icon at the top represents the study currently being processed or the study most recently processed. The Study icons below represent studies processed earlier.

The white triangle indicates the study icon linked to the study information currently on-screen.



The following items appear on the Studies screen:

- **Study icons** each represent one study. Scroll the study icon list to view additional studies. To display the results of any completed study, simply touch the icon for the study. The appearance of the study icon indicates the status of the case; the various icons that may appear are shown in the table on page 16.
- **Study Information** appears for each case of films as they are scanned and processed. The Study Information includes the R2 ID, Receive Time (the time scanning began for the study), and current Status, as well as thumbnail images of the films and patient information discussed below.
- Thumbnail film **Images** appear as they are scanned and can be viewed at any time after the system scans the films.
- **Patient Information** includes the patient flash from the scanned film and other data associated with each study (in particular, data imported from a mammography reporting system).
- The **R2 Patient ID** button appears only if your system is configured to use the R2 Patient ID system. Click the button to access the R2 Patient ID database. For more information see '7.3. Using the R2 Patient ID System'.

- The **Search field** allows you to type patient data or a barcode number and quickly find the patient record. You can also activate the Search field with the handheld barcode scanner.
- The **Scanning Protocol** list allows you to select a scanning protocol that matches the number and types of films in your cases. Includes R2 standard scanning protocols and any custom protocols created on site.
- The **Start button** is used to begin scanning and processing a stack of films. When scanning begins, the button changes to Stop.
- The **Status** field, which appears above the Start button, indicates the scanner status, for example, '**Ready**', '**Scanning**', etc.

Scanning and Processing

To scan a case, you must first create a stack of films. The case at the top of the stack is scanned first. You select a scanning protocol based on the type of cases you will be scanning (see '3.1. Working with Films' for more information).

To scan films you simply:

- Arrange the films with a separator sheet on top of each case.
- Organize films and separator sheets in a stack.
- Place the stack in the film input tray.
- Touch the **Start** button.

The scanner picks up the first separator sheet followed by the first film in the stack. A new study icon appears at the top of the list, and a white circle on the icon flashes to indicate that the system is scanning or processing the films. Each separator sheet includes a barcode that the system uses to organize the results. When the system scans the barcode on the separator sheet, the barcode number appears on the Studies screen as the 'R2 ID'. As the films are scanned, the system displays thumbnail images, the patient flash, and any patient information linked to the R2 ID.

When the system finishes processing the case, the Status field changes to 'Completed'. A white arrow on the study icon flashes to indicate that the system is sending study results to the display unit, PACS/workstation, or printer on your network.

⚠ ***Note:*** *Before the study results are sent to the display/archive device, you may be required to 'verify' that the system scanned the films correctly. This option is configured on the Controls Outputs screen. For more information, see '5.4. Outputs Options'.*

The appearance of the study icon indicates the status of the case:

Study Icon	Status
(blinking circle)	Case films are being scanned or processed.
(blinking arrow)	Case results are being sent to a display or archive device.
(blinking question mark)	Scanned images for the case require verification.
(blinking exclamation point)	Case films are being scanned or processed, but a non-fatal fault condition has occurred.
(blinking arrow)	Case results are being transmitted, but a non-fatal fault condition has occurred.
(blinking question mark)	Scanned images for the case require verification, and a non-fatal fault condition has occurred.
	Case is complete, results have been sent.
	Case is complete, but a fault condition has occurred that may require user intervention.
	Case has failed. A fault condition has occurred that requires user intervention.

For more about using the Studies screen, see 'Part 3: Studies'.

System Alerts

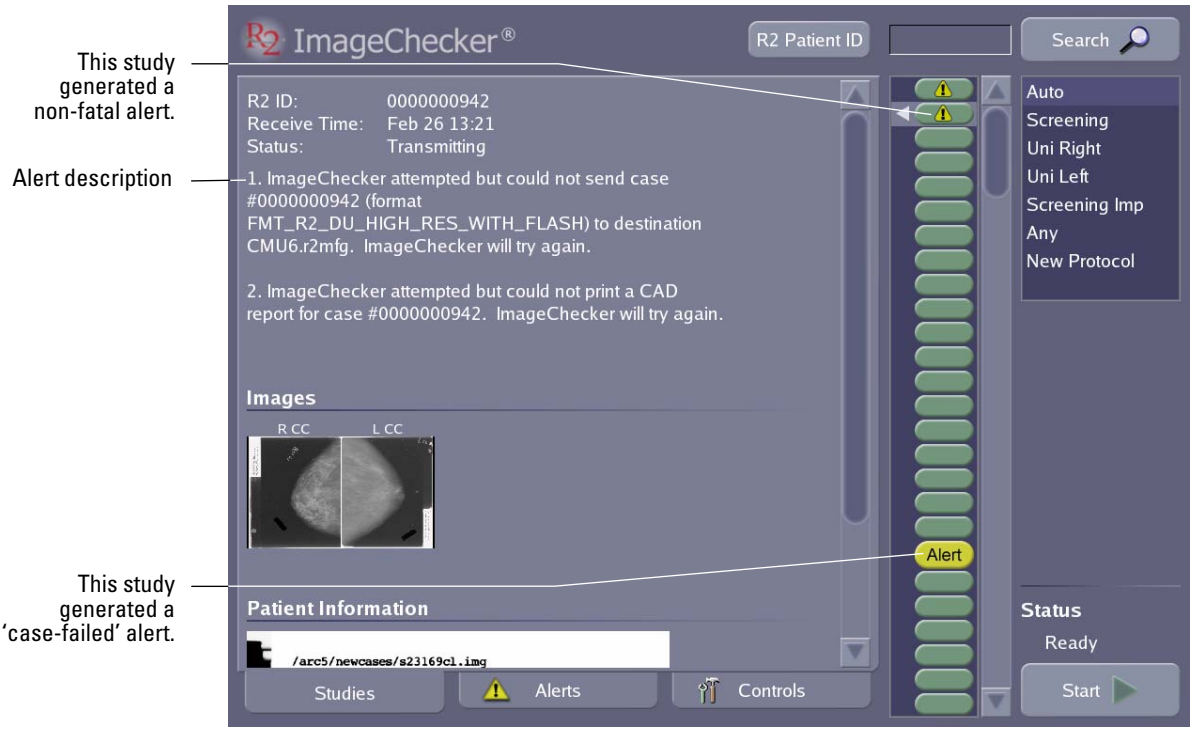
If a problem occurs during scanning or processing a case, or while transmitting case results, the system issues an alert. There are three general types of alerts:

Alert Icon	Status
	A non-fatal fault condition has occurred. This alert appears on the case study icons (see previous table).
	The software has processed the images successfully, but a fault condition has occurred that may require user intervention.
	Case has failed, results have not been sent.

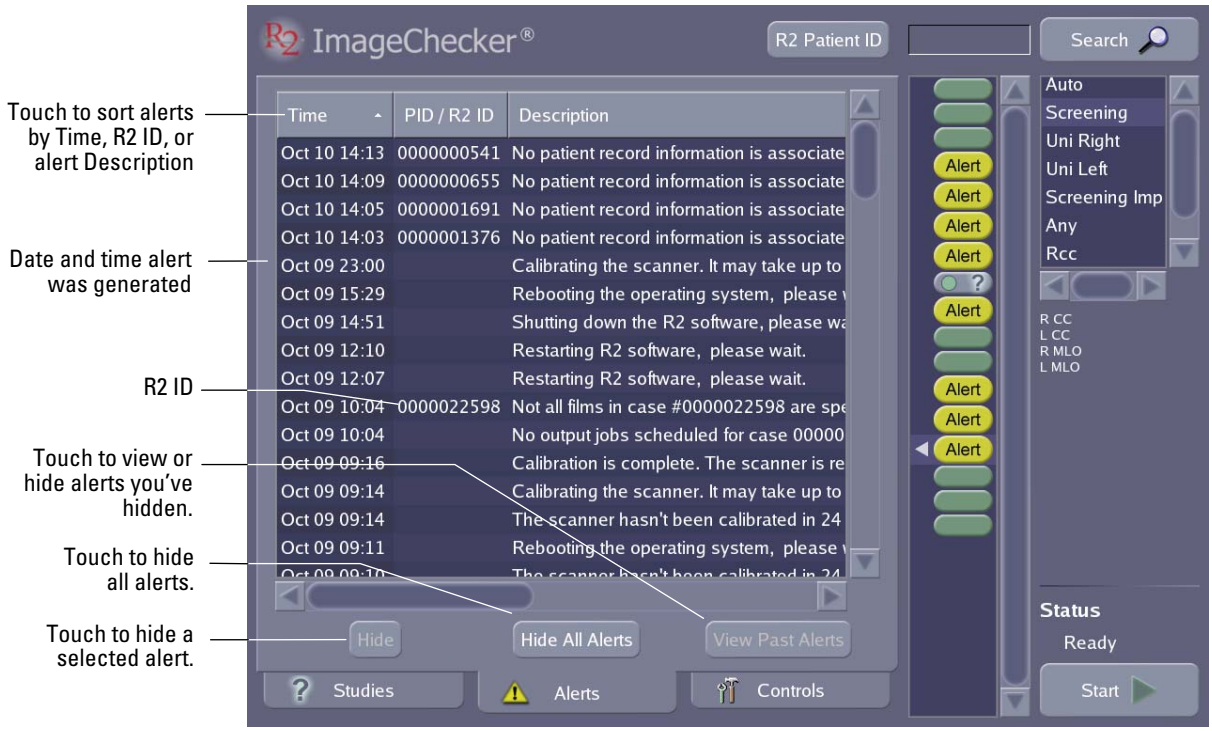
A description of the alert condition appears for the selected study in the area of the screen below the study's R2 ID.

The outcome of any alert condition depends upon the nature of the problem the system has encountered. In the example shown below, the system is experiencing problems as it attempts to send case results to a CheckMate Ultra display unit and to a printer. If after repeated attempts it cannot transmit the case results, the system may issue a 'case-failed' alert and change the study icon accordingly.

The system produces alerts for a variety of reasons. When necessary, the alert description provides instructions for resolving the problem. In some cases you will want to refer to 'Part 4: Alerts' for more information about a particular alert.



When an alert is issued, the yellow alert icon (⚠) appears on the **Alerts** tab at the bottom of the screen. If you touch the **Alerts** tab, you can see recent system alerts.

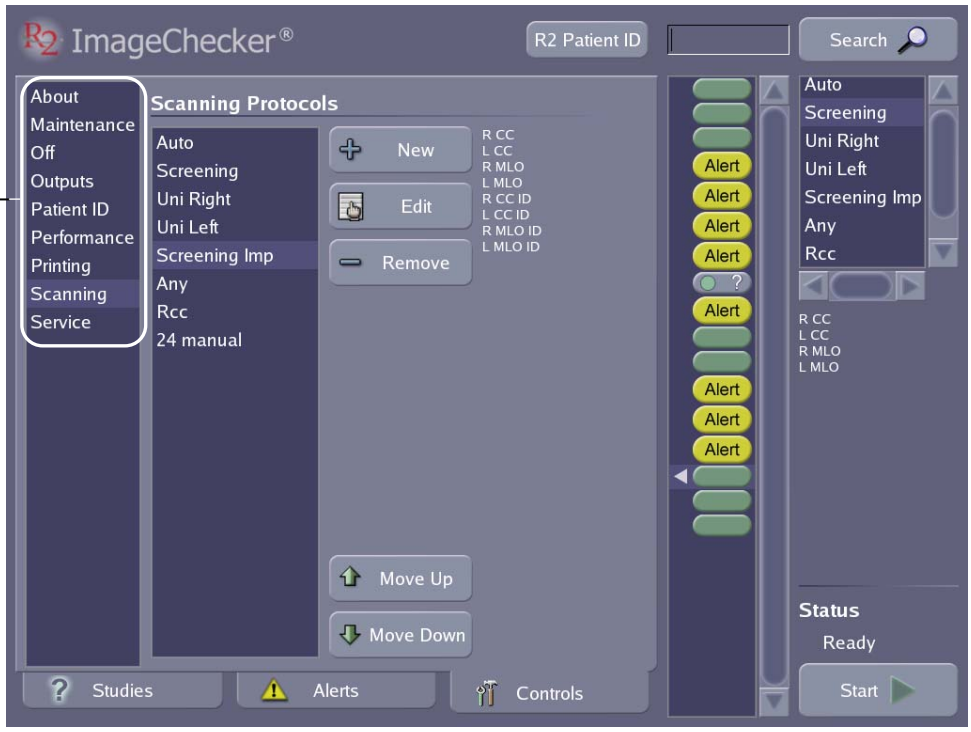

Touch to sort alerts by Time, R2 ID, or alert Description
Date and time alert was generated
R2 ID
Touch to view or hide alerts you've hidden.
Touch to hide all alerts.
Touch to hide a selected alert.
ImageChecker®
R2 Patient ID
Search
Time
PID / R2 ID
Description
Oct 10 14:13 0000000541 No patient record information is associate
Oct 10 14:09 0000000655 No patient record information is associate
Oct 10 14:05 0000001691 No patient record information is associate
Oct 10 14:03 0000001376 No patient record information is associate
Oct 09 23:00 Calibrating the scanner. It may take up to
Oct 09 15:29 Rebooting the operating system, please
Oct 09 14:51 Shutting down the R2 software, please wa
Oct 09 12:10 Restarting R2 software, please wait.
Oct 09 12:07 Restarting R2 software, please wait.
Oct 09 10:04 0000022598 Not all films in case #0000022598 are spe
Oct 09 10:04 No output jobs scheduled for case 00000
Oct 09 09:16 Calibration is complete. The scanner is re
Oct 09 09:14 Calibrating the scanner. It may take up to
Oct 09 09:14 The scanner hasn't been calibrated in 24
Oct 09 09:11 Rebooting the operating system, please
Alert
Auto
Screening
Uni Right
Uni Left
Screening Imp
Any
Rcc
R CC
L CC
R MLO
L MLO
Status
Ready
Start
Hide
Hide All Alerts
View Past Alerts
Studies
Alerts
Controls

When reviewing alerts, you can use the Alerts screen to sort alerts by time issued, R2 ID, or by description. You can also hide one or more alerts.

Controls Screen

The **Controls** screen is used to configure system settings to meet your particular needs, run maintenance procedures, and display system information.

Touch a screen name to display its contents.



For details about the settings, utilities, and information on the **Controls** screen, see 'Part 5: Controls'.

2.4. System Features

This section describes the principal features of the R2 DM system.

Feature Licensing Flexibility

The system features are determined by the licensed options selected by each site, allowing you to invest only in the features you want, as well as add features at a later date. The following features can be obtained by purchasing the appropriate license:

- ImageChecker Film-Screen CAD
- DigitalNow DICOM Export
- Reporting System Interface
- PeerView and PeerView Digital

These features are described further in the following sections.

ImageChecker Film-Screen CAD

The ImageChecker license provides R2 Technology's Gold Standard CAD™ algorithm, which provides the medical-imaging industry's highest sensitivity at any given false-mark rate. The algorithm offers three operating points to accommodate differing radiologist preferences. The performance of the system for each of the three operating points as measured on R2 Technology's *film* database is summarized below:

Operating Point	0	1	2
Calcification Sensitivity	95%	96%	97%
Mass Sensitivity	83%	88%	90%
False Marks per Case	1.0	1.5	2.0

When your system is installed, you can select different operating points for calcifications and masses. For more information, see '2.5. ImageChecker Film-Screen CAD'.

⚠ ***Note:*** *Every time films are rescanned, the image created is subtly different. This difference is of no consequence to a human observer, but slight rotation, shift, and electronic noise differences will cause some CAD marks to vary with each rescan. This is expected behavior.*

⚠ ***Note:*** *If the ImageChecker software has been upgraded to a newer revision since the mammograms were first processed, the resulting CAD marks may be different if a newer algorithm is used to process the cases.*

DigitalNow DICOM Export

R2 film-scanning platforms can send digitized film images to a DICOM-conformant archiving system for future review. Sites using full-field digital mammography can scan prior studies and compare those priors with the current digital study on a softcopy review workstation. Sites planning to move to digital in the near future can plan ahead and send the digitized images to an archive system now, and retrieve them for comparison later to current digital studies.

R2 systems configured with DigitalNow utilize the separator sheet barcode ('R2 ID') for identifying the patient associated with the digitized film images. This allows for

the proper identification, storage, and retrieval of digitized film images in the archive system.

The system can be configured to generate 50 or 100 micron output images, or both. For digitized film images, the processing units perform dynamic window leveling on each image, as well as blacken image areas that lie outside the film edges.

DigitalNow enables sites with ImageChecker CAD to archive CAD marks to PACS, if desired. The CAD marks can also be printed and archived with other paper-based patient records.

⚠ ***Important!*** *From time to time, be sure to check images received at the review workstation/PACS to confirm that films continue to be properly scanned and digitized.*

Reporting System Interface

R2 DM systems can interface with PenRad, MRS, and MagView mammography reporting systems. The R2 software retrieves patient information from the reporting system database – such as the patient name, medical record number, and birth date – and links this information to the patient images. Patient information can be printed on the CAD Results Report (see page 50), and on the Reimbursement Barcode Report (see page 22).

To link reporting system records to R2 Technology images, you use a keyboard or barcode scanner to enter the R2 ID from the separator sheet that will be used when the system scans the films.

⚠ ***Important!*** *Be sure to enter the R2 ID into the reporting system before entering it on the R2 film-scanning platform.*

PeerView and PeerView Digital

PeerView™ and PeerView™ Digital are optional features that help radiologists better understand why a region of interest was marked. PeerView and PeerView Digital display a close-up, high-resolution section of the image and highlight physical features found by the algorithm, facilitating the radiologist's reassessment of the mammograms.

- PeerView is licensed on CheckMate Ultra display units and Mammolux motorized viewers. When licensed, PeerView asks the R2 DM system to send the additional high-resolution CAD information to the display unit.
- PeerView Digital is licensed on the DM system. When licensed, PeerView Digital creates extra CAD information in the Mammography CAD SR output, viewable on some softcopy review workstations. It displays a close-up, high-resolution section of the image, highlights physical features found by the algorithm, and produces measurements of the physical features.

Other System Features

In addition to the licensed features, the R2 DM system includes the following standard features:

- Establish Patient Identification
- Automatic Film Marker Identification
- Reimbursement Barcode Report

These features are described further below.

Establish Patient Identification

Each case fed into the R2 film-scanning system must have its own separator sheet. The R2 system uses the barcoded R2 ID on the separator sheet to associate the patient films with the images in the system.

When processing a patient's films, you write the R2 ID from the separator sheet on the patient file. If using a mammography reporting system, you also enter the R2 ID into the appropriate field in the patient's reporting system record.

⚠ ***Important!*** *It is a good idea to record the R2 ID on the outside of the patient film jacket. In addition, it is critical that ImageChecker CAD users keep the separator sheet with the films until after the radiologist has read the films and CAD results.*

Automatic Film Marker Identification

If your four, standard-view films were processed using R2-supported lead markers, and the markers are well-placed, you can scan the films using Auto film detection mode. This means your cases can consist of any number of films (up to four), and you can place them in the scanner in any orientation (e.g., rotated or emulsion side up or down) and in any order.

This timesaving feature enables sites to scan as many cases as possible in as short a time as possible. The lead markers must be a supported type, they must not be attached with putty or other opaque substances, and they must be placed properly (as per MQSA standards). R2-suported lead markers are available from Hologic | R2, Livingston Products, Siemens, Techno-Aide, or All-Craft Wellman. For the supported marker types, see 'R2-Supported Lead Markers' on page 30.

Reimbursement Barcode Report

The Reimbursement Barcode Report is a listing of all separator sheet barcode numbers scanned in a specific time period. You can schedule it to run monthly, weekly, or on demand for a specified date range.

The report lists the date, the cases processed on that date, and the time the case was processed. This can be correlated to the patient using the R2 barcode number written in the patient file, thereby completing the reimbursement audit trail.

The report lists only cases that were successfully. When using a mammography reporting system, additional patient information can be listed with each report entry. For an example printout, see 'Printing a Reimbursement Barcode Report' on page 76.

2.5. ImageChecker Film-Screen CAD

When configured with the ImageChecker CAD license, the R2 DM system applies R2 Technology's Gold Standard CAD software algorithm to mammography images in order to detect regions of the breast that may be cancerous. ImageChecker CAD identifies and marks regions of interest that may warrant a second review by the radiologist, thereby helping to minimize observational oversights.

R2 Technology's ImageChecker CAD software was the first computer-aided detection (CAD) software approved by the FDA for full-view diagnostic and screening mammograms. Since that first approval, the ImageChecker software has been refined many times, resulting in an algorithm that is highly sensitive with few false marks.

This section describes features available for systems configured with the ImageChecker Film-Screen CAD license.

Intended Use

The R2 DM system, when configured with the ImageChecker Film-Screen CAD license, identifies and marks regions of interest on routine screening and diagnostic mammograms to bring them to the attention of the radiologist after the initial reading has been completed. The system assists the radiologist in minimizing observational oversights by identifying areas on the original mammogram that may warrant a second review.

CAD Marks

The ImageChecker software provides three types of CAD marks (Mass, Calc, and Malc) that can appear in the results. Each mark identifies a region of interest for the radiologist to review.

Calc – Marks regions suggestive of calcifications.

Mass – Marks regions suggestive of masses or architectural distortions.

Malc – Composite mark indicates an overlap of Calc and Mass marks.

EmphaSize

ImageChecker CAD also includes EmphaSize™ variable-size marks. The feature allows the display unit or review workstation to display marks of variable size that correlate to feature significance. When the algorithm determines that a region is more significant, the CAD mark appears larger, indicating that the region should receive more emphasis from the radiologist.

CAD Operating Points

The ImageChecker software allows each site to choose between three different operating points (i.e., CAD algorithm thresholds): operating point 2, which emphasizes sensitivity, operating point 0, which emphasizes a low false-mark rate, and operating point 1, which is an intermediate point.

The table below gives the sensitivity and false-mark rate values for the three operating points for version 8 ImageChecker applications, as measured on R2 Technology's large *film* test database of biopsy-proven malignancies and confirmed normal cases for the four standard views (RCC, LCC, RMLO, and LMLO).

Operating Point:	2	1	0
Calcification Cases (n = 588)			
Mean Sensitivity[1]	97%	96%	95%
95% Confidence Interval	95.5–98.3%	94.0–97.2%	93.1–96.7%
Mass Cases (n = 767)			
Mean Sensitivity[1]	90%	88%	83%
95% Confidence Interval	87.7–92.0%	85.6–90.2%	79.8–85.2%
Overall (n = 1355)			
Mean Sensitivity[1]	93%	91%	88%
95% Confidence Interval	91.5–94.3%	89.7–92.7%	86.2–90.0%
False-Positive Marks[2]			
Calcification FP/Image	0.16	0.12	0.09
Mass FP/Image	0.35	0.25	0.17
Total False-Positive Marks/Case	2.0	1.5	1.0
Specificity[2]	24.5%	35.1%	48.3%
95% Confidence Interval	20.5–28.5%	30.6–39.5%	43.7–53.0%

1. 'Sensitivity' refers only to the sensitivity of the CAD algorithm, not to the sensitivity of the radiologist using the device.

2. 'False-Positive' and 'Specificity' data were developed from a review of 445 confirmed normal cases (defined as those with a subsequent normal screening study). 'FP/Image' refers to the average number of false-positive marks per image measured on normal cases. 'Specificity' refers to the percentage of normal cases that, when processed, show no CAD marks.

- **Operating point 2** focuses on sensitivity. It gives the best performance for marking regions of interest (i.e., CAD sensitivity), with a higher false-mark rate. It is suited for sites that want the system to be as sensitive as possible, regardless of the higher false-positive mark rate.
- **Operating point 1** represents an intermediate point. Improvements in the algorithm have allowed points 0 and 2 to be set quite far apart, and some sites may want intermediate behavior from the CAD algorithm.
- **Operating point 0** trades off a lower false-mark rate for a lower overall sensitivity. This operating point is suited for sites that prefer the system to display the fewest false marks.

You can choose a different operating point for calcifications than for masses. For example, if you want high sensitivity for calcifications but a moderate balance between sensitivity and false positives for masses, choose operating point 2 for calcifications and operating point 1 for masses.

Each system is shipped with a default set of operating points for both masses and calcifications. You can discuss the choices that are right for your site with your Applications Specialist or, if you would like to change configurations, contact your Hologic | R2 Technical Service Representative.

⚠ ***Note:*** *To determine false-mark rates, R2 Technology processes normal screening cases (defined as those with a subsequent normal screening study) through the ImageChecker software and measures the number of false marks per image. More extraordinary screening cases, such as those with additional views, and diagnostic studies, may have a very different make-up of images and, as such, may produce results that fall outside the measured normal case mark rate. Since the mark rate is measured per image, a larger number of images in a case should correspond on average with a higher total mark count for that case. However, while clinical experience demonstrates some variation in mark rates, R2 Technology has not found the false-mark rate to vary dramatically when averaged over a large number of cases.*

⚠ ***Note:*** *A recent revision to the DICOM standard has resulted in a nomenclature change. The terms, 'thresholds A, B, and C', used in previous R2 Technology products (software version 8.1 and earlier), have been replaced by 'operating points 2, 1, and 0'. Also note that earlier versions of the ImageChecker application (before version 8) produce slightly different performance results. For further information, see the manuals provided with those systems.*

Number of CAD Marks

The software limits the number of CAD marks for each image and case. The actual number of CAD marks produced depends upon the individual case and the operating point selected for the CAD algorithm. Note that the specificity of the device at the most sensitive operating point is no lower than 24.5% (24.5% of normal cases show no marks).

	Per Image Limit	Per Case Limit
Standard four views (RCC, LCC, RMLO, LMLO)	3 Calc marks 2 Mass marks 2 Malc marks	8 Calc marks 4 Mass marks 4 Malc marks
Extra views	3 Calc marks 2 Mass marks 2 Malc marks	Dependent upon the number of images*

*For cases with more than four views, the maximum number of marks per case depends upon the number of images in the case (up to 24 images per case).

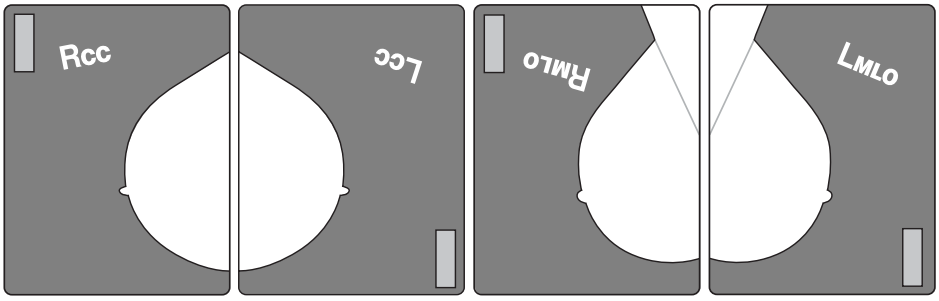
2.6. System Inputs and Outputs

R2 software version 8.5 supports up to 24 images per case. All scanned film images can be viewed at a digital review workstation and/or archived on a PACS. Other devices, such as the CheckMate Ultra display unit, can display up to four views per case, if the views are supported by the display unit.

CAD-Supported Views

If your system has the ImageChecker license, all images are CAD-processed if the views and any modifiers are supported by the software. The four 'standard views' processed automatically by the ImageChecker software are:

- LCC – Left Cranio-Caudal
- RCC – Right Cranio-Caudal
- LMLO – Left Medio-Lateral Oblique
- RMLO – Right Medio-Lateral Oblique



The Four Standard Views

In addition, systems with ImageChecker CAD can process the 'equivalent' and 'reversed equivalent' views, as long as they do not include unsupported view modifiers (see next page). However, CAD results for certain views and view modifiers cannot be displayed or printed on some output devices. The following table shows the CAD-supported views and the output devices that can accept these views.

CAD-Supported Views Standard View	View Label	DICOM Workstation, PACS	Display Unit Printer, CAD SC
Cranio-Caudal	CC	●	●
Medio-Lateral Oblique	MLO	●	●
Equivalent View			
Medio-Lateral	ML	●	●
Exaggerated Cranio-Caudal	XCC	●	●
Cranio-Caudal Exaggerated Laterally	XCCL	●	●
Cranio-Caudal Exaggerated Medially	XCCM	●	●
Reversed Equivalent View			
Latero-Medial	LM	●	—
Latero-Medial Oblique	LMO	●	—
Cranio-Caudal From Below	FB	●	—
Superolateral to Inferomedial Oblique	SIO	●	—

● = Output supported to this device — = Output not supported to this device or format

In the preceding table, 'Display Unit' refers to a CheckMate Ultra display unit or Mammolux motorized viewer. These devices (and the R2 postscript printer) can display (or print) no more than four views per case.

- When multiple images of the same view are present in a case, the *last* image of a specific view will be sent to the display unit or printer.
- When a case includes multiple equivalent views, the system chooses the four views sent to the display unit and printer based on the following preference order:

Preference Order	CC Equivalent	MLO Equivalent
1	CC	MLO
2	FB*	ML
3	XCC	LM*
4	XCCL	LMO*
5	XCCM	SIO*

*Indicates a reversed view, not available for display units, printouts, or CAD SC output.

View Modifiers

View modifiers can be added to describe any supported view, however, some modifiers are not supported for CAD processing. Using a non-supported modifier will prevent CAD processing a supported view. The following table lists the supported DICOM view modifiers and indicates which are supported for CAD processing.

View Modifier	Label	View Modified	CAD Support
Axillary Tail	AT	MLO	●
Cleavage	CV	CC	
Partial View	(none)	Any	
Rolled Lateral	…RL	Any	●
Rolled Medial	…RM	Any	●
Rolled Inferior	…RI	Any	●
Rolled Superior	…RS	Any	●
Magnification	M…	Any	
Spot Compression	S	Any	
Implant Displaced*	ID	Any	●
Implant Present	(none)	Any	
Tangential	TAN	Any	●

* Implant-displaced views with a maximum of 2.5 cm (1 in) of implant imaged.

⚠ ***Note:*** *The Implant Present and Partial View modifier labels are NOT added to the view description, but are present in the DICOM header.*

Digital Image Output Options

The R2 DM system can send files with any of the following formats to a PACS or review workstation.

- **DigitalNow MG Image:** This is a traditional mammography image format where the image is comprised of Natural Pixel Values, the values actually created by the film scanner.
- **DigitalNow ELC™ Enhanced MG Image:** This image has been processed using R2's proprietary ELC algorithm to enhance contrast within local regions of the images. This format was developed specifically to increase the conspicuity of low-contrast microcalcification clusters.
- **Mammography CAD SR:** This is the DICOM standard format for CAD results. CAD SR files are generally useful only when viewed with the images on an advanced FFDM or PACS workstation. PACS support for storing Mammography CAD SR objects is increasing, and IHE support for Mammography CAD SR is beginning to result in more PACS workstations being able to display Mammography CAD SR content.
- **CAD SC Image:** This is a Secondary Capture image object that includes the CAD results burned into a montage of low-resolution images, similar to the images that R2 sends to motorized viewers or CheckMate display units. This form of output is useful for PACS that do not support CAD SR. Not supported for reversed views.

DigitalNow images can be created as either 50- or 100-micron image files. The file sizes can depend upon the film size and resolution.

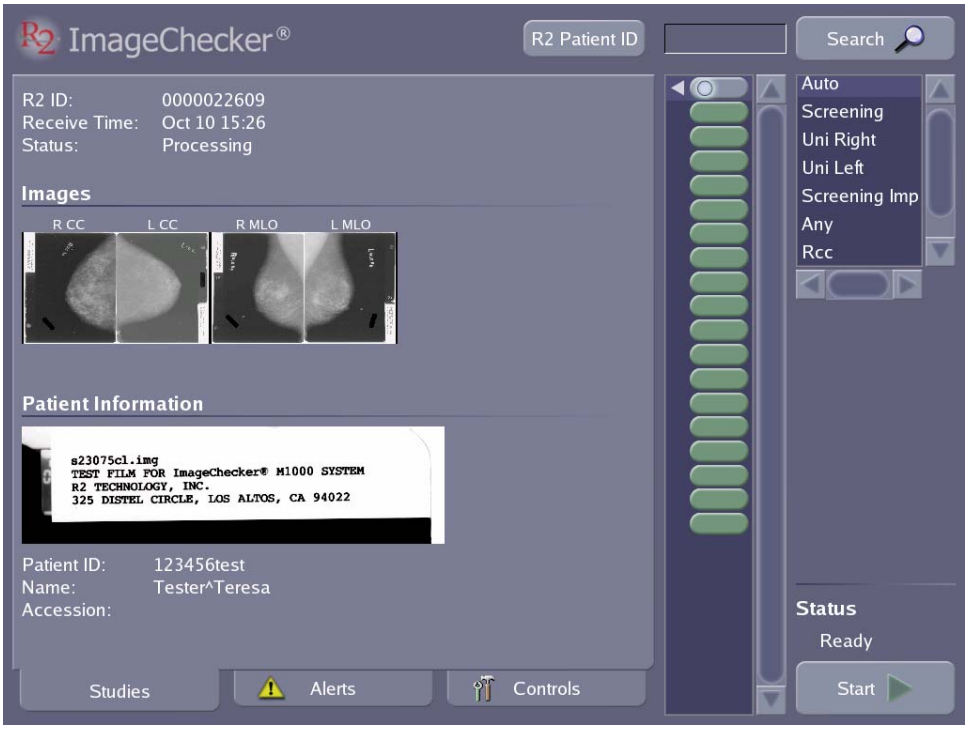
Film Size	50µ Image	100µ Image
18 × 24 cm	35 MB	8.6 MB
24 × 30 cm	50 MB	14.4 MB

Part 3: Studies

- 3.1. Working with Films
- 3.2. Preparing Cases to Be Scanned
- 3.3. Scanning with the Auto Protocol
- 3.4. Scanning with a Manual Protocol
- 3.5. Scanning with the Any Protocol
- 3.6. Adding Cases to the Stack
- 3.7. Stopping Scanning and Removing a Case
- 3.8. Viewing Study Information
- 3.9. Verifying Scanned Cases
- 3.11. Printing CAD Results
- 3.12. Searching for a Study
- 3.13. Using Queue Manager

Part 3 provides instructions for working with films, scanning cases, working with scanned images, displaying study results, and searching for a study.

For most operations you will be using the **Studies** screen, which is shown below:



3.1. Working with Films

To use the system successfully, please read and understand the film requirements and modes used to scan the films.

Film Requirements

All films must meet the following requirements:

- Original films only – no copies
- No bent, damaged, or curled films
- 18 × 24 cm or 24 × 30 cm standard full-field views
- No sticky residue, wax or grease pencil marks on films
- No labels over the edges of films, or curled labels
- MQSA or other required standards

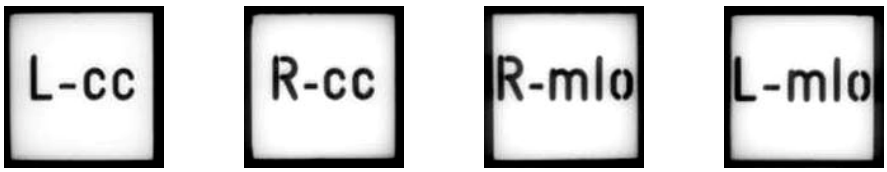
Because the scanner uses suction cups to lift each film into the scanner, anything that interferes with the suction cups, such as a patient label placed improperly or a wax pen mark, may cause the scanner to drop films.

R2-Supported Lead Markers

The R2 film-scanning platform can scan any film-based mammograms that meet the requirements listed above. However, when you use R2-supported lead markers with the four standard views, there is an additional degree of convenience: you can load the films in any orientation and in any order. (For more information, see 'Scanning Protocols' on page 32.)

R2-supported lead markers are available from Livingston Products, Siemens, Techno-Aide, All-Craft Wellman, and Hologic | R2. An illustration of the supported type from each company is shown below.

Livingston – www.livingstonproducts.com

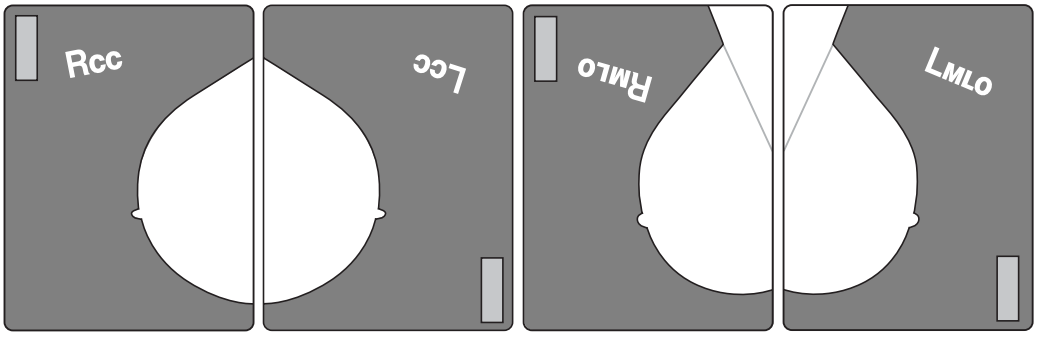


Siemens – www.siemens.com

Techno-Aide – www.technoaide.com
All-Craft Wellman – www.all-craftwellman.com
Hologic | R2 – www.r2tech.com

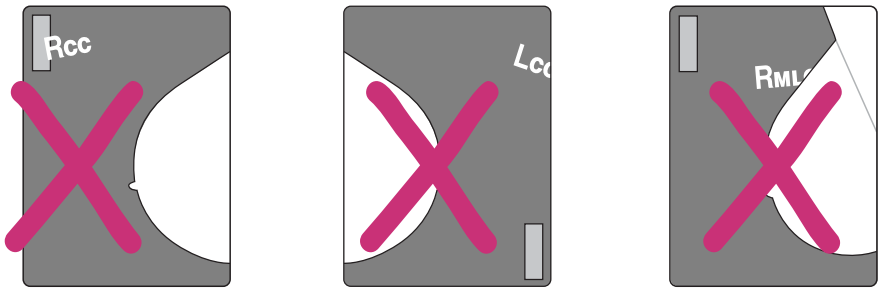
Lead Marker Placement

Correct placement of the lead markers is essential for optimal results. The following examples show lead markers that are easy for the system to read, and that are not touching the patient ID label, the breast tissue, or the film edge.



Correct Auto Protocol Lead Marker Placement

The following lead markers are incorrectly placed, as explained below:



Incorrect Auto Protocol Lead Marker Placement

Separator Sheets

The R2 DM system is shipped with 1,000 separator sheets. Run through all sheets on a rotating basis to ensure that patient barcode numbers are not reused before the images are deleted from the system.

The separator sheets are sturdy and able to withstand a great deal of use. However, be sure to store them flat, do not write on them with anything greasy or waxy, do not put tape on the edges, and keep them clean. Most importantly, do not obscure the barcode or the barcode number.

To order additional separator sheets, contact your Hologic | R2 Account Manager or Technical Support.

Scanning Protocols

The system includes six preconfigured scanning protocols: Auto, Screening, Uni Right, Uni Left, Screening Imp, and Any. You can also create your own site-specific scanning protocols, see '5.8. Scanning Protocols'.

The default (i.e., preselected) scanning protocol is Auto. You can change the default scanning protocol using the Controls Scanning screen (as described on page 79).

Auto Protocol

When using the Auto protocol, the system recognizes the lead markers and uses them to properly identify, orient, and process films with the four standard views.

You can load the films for each case in any order (e.g., RMLO, LCC, RCC, LMLO) and in any orientation (e.g., rotated 180°, emulsion side up or down). The system automatically scans all films in the stack. Each case in the stack can have any number of films up to four. The system automatically adjusts if there are fewer than four films. However, in Auto mode, the system will not process duplicate views within the same case (e.g., two RCC films).

After you touch the Start button, the system processes all cases in the stack, up to a maximum of 20 cases with four films per case.

Manual Protocols

R2 provides four preconfigured Manual scanning protocols: Screening, Uni Right, Uni Left and Screening Imp. Each protocol requires you to load films with specific views in a predefined sequence. For the views used with each predefined scanning protocol, see '3.4. Scanning with a Manual Protocol'. You can also define custom Manual scanning protocols for your site, or alter the included protocols as needed.

When using a Manual scanning protocol, the system does not recognize the lead markers. Instead, it relies on you loading the films:

- With the views specified by the selected scanning protocol.
- In the correct order – defined by the selected protocol.
- In the correct orientation – emulsion (dull) side down, landscape for small films, portrait for large films.
- With the patient flash in alternating opposite corners – if the protocol specifies alternating sides (upper right and lower left for small films, upper left and lower right for large films).

The system also assumes that each study includes the same film views (as defined by the selected protocol). If you are using a Manual protocol (because, for example, you don't use R2-supported lead markers) and the cases to be scanned include different numbers of films or different views, create stacks of like cases and scan them separately using the appropriate scanning protocol.

When using a Manual scanning protocol, as with the Auto protocol, the system automatically scans all cases in the stack. When scanning is complete, the system switches back to the default scanning protocol, as configured on the Controls Scanning screen.

Any Protocol

This special scanning protocol allows you to scan any number of films (up to 24 per case) in any order and orientation. When using the Any protocol, you must identify all views manually after the case is scanned.

Choosing a Scanning Protocol

The scanning protocol you choose depends on the views present in the case, and the condition of the films. In general, you will want to select a scanning protocol that suits about 90% of the cases in the stack, which will minimize the adjustments that you have to make after scanning. However, sometimes it may be faster simply to scan with the Any protocol and correct the images afterwards.

⚠ ***Important!*** *Many scanning errors, including scanning films in the wrong order or scanning a film in the wrong orientation, can be overcome using the GreenLight Image Correction feature. When in doubt, scan the films as best you can and fix any problems after scanning. However, note that you cannot use GreenLight to correct images produced from films scanned from different patients under a single separator sheet; those films will have to be re-scanned using the appropriate number of separator sheets.*

The following table provides basic guidelines for selecting a scanning protocol.

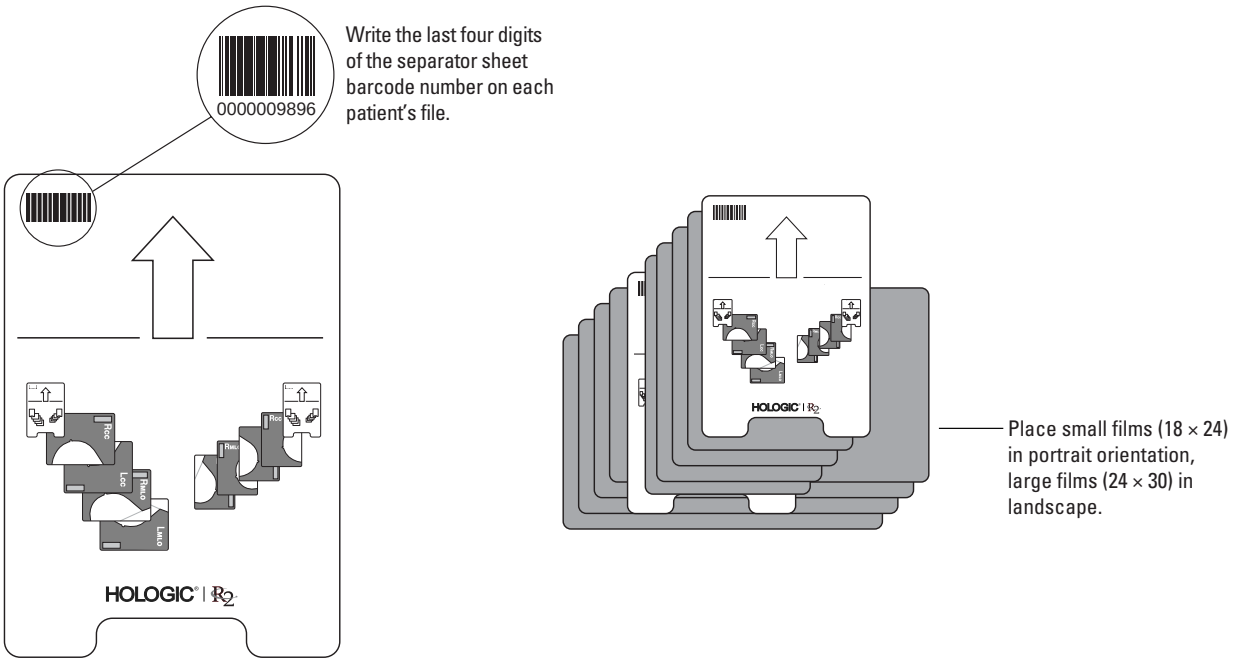
If your films ...	Then see ...
• Are the four standard screening views (RCC, LCC, RMLO, LMLO) and • Were taken using an R2-supported lead marker (those shown on page 30) and • Have well-placed lead markers	3.3. Scanning with the Auto Protocol
In all cases include the same number and type of views, and: • Have unsupported, missing, or bad lead markers, or • Have incorrectly placed lead markers (e.g., over a breast image, under an ID label, or only partly on film, as shown on page 31), or • Have non-standard views or views with modifiers, or • Have more than four views per case	3.4. Scanning with a Manual Protocol
• Include views that do not conform to any available scanning protocols	3.5. Scanning with the Any Protocol

3.2. Preparing Cases to Be Scanned

Use this procedure to create a stack of cases to be scanned.

1 Place a separator sheet on top of each film case.

2 Write the last four digits of the separator sheet barcode number on the patient's file.


Write the last four digits of the separator sheet barcode number on each patient's file.
0000009896
HOLOGIC
Place small films (18 × 24) in portrait orientation, large films (24 × 30) in landscape.

Creating a Stack of Cases

3 Create a neat stack of films and separator sheets. Observe the following guidelines.

- Put small-film cases at the top of the stack, mixed-film cases in the middle, and large-film cases on the bottom.
- If the number of films in the case does not match any of the defined scanning protocols, use the Any protocol.
- Use the correct number of films per case, as specified by the selected scanning protocol.
- If you plan to scan with the Auto protocol, you can use from one to four films, as long as they have supported lead markers and are from the four standard views with no duplicate views. You can arrange the films in any order and in any orientation. See '3.3. Scanning with the Auto Protocol'. Load only the four standard views with no duplicates.
- If you plan to scan with a Manual protocol, you must arrange the films exactly as defined by the desired scanning protocol. See '3.4. Scanning with a Manual Protocol'.
- If you plan to use the Any protocol to scan a special case (one that doesn't conform to any available scanning protocol), then see '3.5. Scanning with the Any Protocol'.

⚠ ***Note:*** *If you make a mistake when preparing a case for scanning, you can sometimes correct it after scanning is complete via the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.*

3.3. Scanning with the Auto Protocol

Use this procedure to scan cases using R2 Technology's Automatic Film Marker Identification (AFMI) feature. The Auto protocol accepts up to four films per case. You can scan with the Auto protocol if all cases in the stack include only the four standard mammography views (RCC, LCC, RMLO, LMLO), and were processed using a supported lead markers (those shown on page 30) that were well-placed.

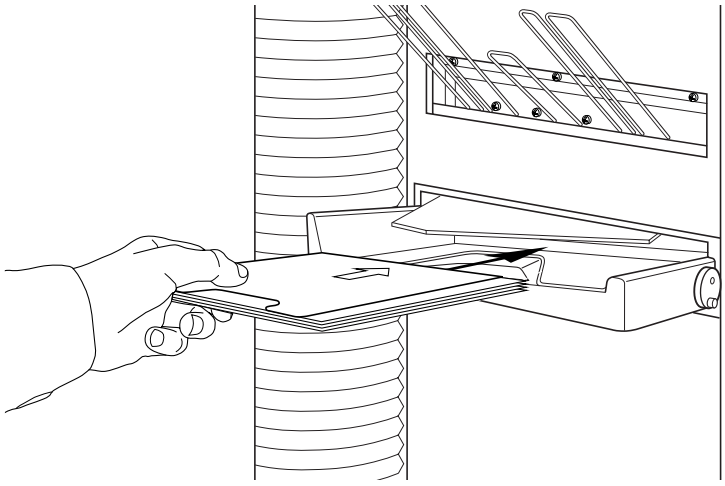
- For cases that do not meet these criteria, but conform to a different scanning protocol, see '3.4. Scanning with a Manual Protocol'.
- For cases which do not confirm to any defined scanning protocol, see '3.5. Scanning with the Any Protocol'.

⚠ ***Important!*** *The Auto protocol does not support duplicate views (for example, two RCC films or two LMLO films). Use a Manual protocol or the Any protocol for cases with duplicate views.*

▶ **To scan with the Auto protocol**

1. Prepare the cases to be scanned as described in '3.2. Preparing Cases to Be Scanned'. You can arrange the films of the four standard views in any order and in any orientation.
2. Load the stack into the input tray. Insert the stack with:
   - The arrow on the top separator sheet pointing into the scanner.
   - The leading edges of the films and separator sheets aligned flush.

   You can load up to 100 sheets – including films and separator sheets – up to 20 four-film cases.



Loading Films

3. Verify that **Auto** is selected in the Scanning Protocol list on the Studies screen.

   ⚠ ***Note:*** *You cannot change the scanning protocol if a case is currently being scanned.*
4. Touch **Start**. The system status changes from 'Ready' to 'Scanning', and the **Start** button becomes a **Stop** button.

After the system scans the first film, a new study icon appears at the top of the study list, and a white circle on the icon flashes to indicate that the films are being processed. If you touch this icon, you can monitor the progress of the study as the films are processed. There are three possible outcomes:

- **Success**: If the system processes the case successfully and verification of cases is not required, then the system automatically sends the study results to the output device (display unit, printer and/or PACS archive). An arrow on the icon flashes to indicate that the system is sending the results. After the system sends the results, the icon appears solid green.
- **Verification Required**: If verification of cases is required, then you must review the scanned image thumbnails and patient information and confirm that the results are acceptable. If no Alert has been issued, then the Done button appears on the Studies screen. When you touch Done, the system sends the results to the output device (display unit, printer and/or PACS archive).
- **Alerts**: If the study icon is replaced with an Alert icon, you may be required to take corrective action. In many situations instead of rescanning the case, you can often correct the alert and reprocess the images via the Image Correction screen.

For more information, see '3.9. Verifying Scanned Cases'. For information on alert messages, see 'Part 4: Alerts'.

5 When the cases have been scanned successfully, put the films and corresponding separator sheets together in the patient folders for hanging.

⚠ ***Note:*** *If the system has been configured to use a different scanning protocol by default (on the Controls Scanning screen), then after scanning a stack of films, the system returns to the default protocol.*

3.4. Scanning with a Manual Protocol

When you use a Manual scanning protocol, each case in the stack must include the correct number and type of film views, as defined in the protocol. You may also need to use a Manual protocol if films:

- Have unsupported, missing, or bad lead markers, or
- Have incorrectly placed lead markers (e.g., over a breast image, under an ID label, or only partly on film, as shown on page 31), or
- Have non-standard views or views with modifiers, or
- Have more than four views per case

If one of the cases in the stack has any of the characteristics listed above and does not have the number of film views specified in any existing Manual protocol, use procedure '3.5. Scanning with the Any Protocol' for that case.

The system ships with four predefined Manual scanning protocols.

Predefined Manual Scanning Protocols	Views Included
Screening	RCC LCC RMLO LMLO
Uni Right	RCC RMLO RXCC
Uni Left	LCC LMLO LXCC
Screening Imp	RCC LCC RMLO LMLO RCC ID LCC ID RMLO ID LMLO ID

Your system may have additional user-created scanning protocols specific to your site. For more information, see '5.8. Scanning Protocols'.

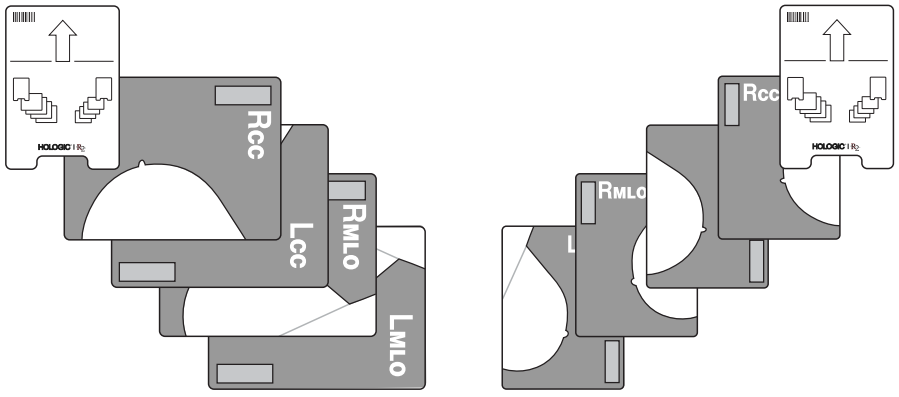
For a list of supported views and modifiers, see 'CAD-Supported Views' on page 26.

▶ To scan with a Manual protocol

1 Prepare the cases to be scanned as described in '3.2. Preparing Cases to Be Scanned'.

2 Arrange the films and their separator sheets in the order shown on the screen below the selected scanning protocol, and with the orientation shown below.

Orientation
- Emulsion (dull) side down
- Small: landscape
- Large: portrait.

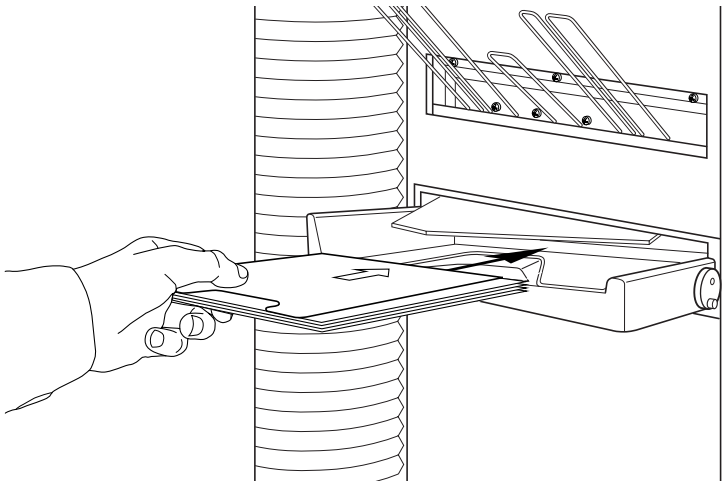


⚠ ***Important!*** *When using a Manual scanning protocol, use the same film views for all cases in the stack, and arrange the films in the order defined by the selected protocol.*

3 Load the stack into the input tray. Insert the stack with:

- The arrow on the top separator sheet pointing into the scanner.
- The leading edges of the films and separator sheets aligned flush.

You can load up to 100 sheets – including films and separator sheets – up to 20 four-film cases.



Loading Films

4 Touch the desired scanning protocol. In the example shown at left, Screening is selected. The views defined for the selected protocol are displayed below the protocol list.

⚠ ***Note:*** *You cannot change the scanning protocol while a case is being scanned.*

5 Touch **Start**. The system status changes from 'Ready' to 'Scanning', and the **Start** button changes to **Stop**.

6 A new study icon appears at the top of the study list, and a white circle on the icon flashes to indicate that the films are being processed. If you touch this icon, you can monitor the progress of the study as the films are processed. There are three possible outcomes:

- **Success:** If the system processes the case successfully and verification of cases is not required, then the system automatically sends the study results to the output device (display unit, printer and/or PACS archive). An arrow on the icon flashes to indicate that the system is sending the results. After the system sends the results, the icon appears solid green.
- **Verification Required:** If verification of cases is required, then you must review the scanned image thumbnails and patient information and confirm that the results are acceptable. If no Alert has been issued, then the Done button appears on the Studies screen. When you touch Done, the system sends the results to the output device (display unit, printer and/or PACS archive).
- **Alerts:** If the study icon is replaced with an Alert icon, you may be required to take corrective action. In many situations instead of rescanning the case, you can often correct the alert and reprocess the images via the Image Correction screen.

For more information, see '3.9. Verifying Scanned Cases'. For information on alert messages, see 'Part 4: Alerts'.

7 When the cases have been scanned successfully, put the films and corresponding separator sheets together in the patient folders for hanging.

⚠ ***Note:*** *If the system has been configured to use a different scanning protocol by default (on the Controls Scanning screen), then after scanning a stack of films, the system returns to the default protocol.*

3.5. Scanning with the Any Protocol

Use the Any protocol to scan cases that do not conform to an existing scanning protocol, for example, if the case has missing films, extra films, or views not included in any existing scanning protocol.

The Any protocol contains no predefined views. This allows you to scan any number of films (up to 24) with any type of view and later identify the views manually once the case has been scanned.

A neat and ordered stack can save time spent adjusting the image orientation after scanning. Keep the following in mind:

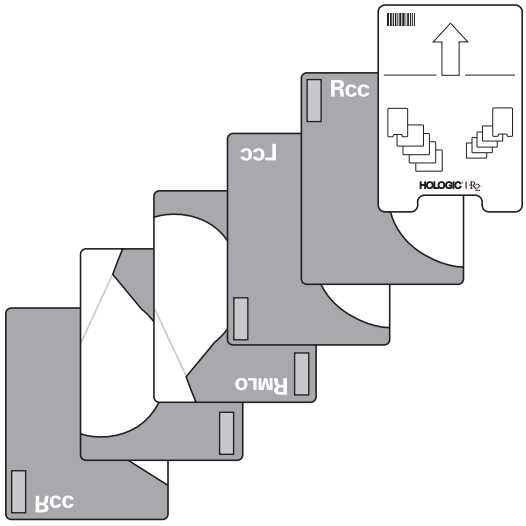
- Remove films from the stack that would normally be discarded rather than saved (for example, technical retakes).
- Orienting the films correctly in the stack saves time adjusting the orientation later via the Image Correction screen.

▶ To scan with the Any protocol

1. Prepare the case to be scanned as described in '3.2. Preparing Cases to Be Scanned'.
2. Place the separator sheet on top of the stack for each case.

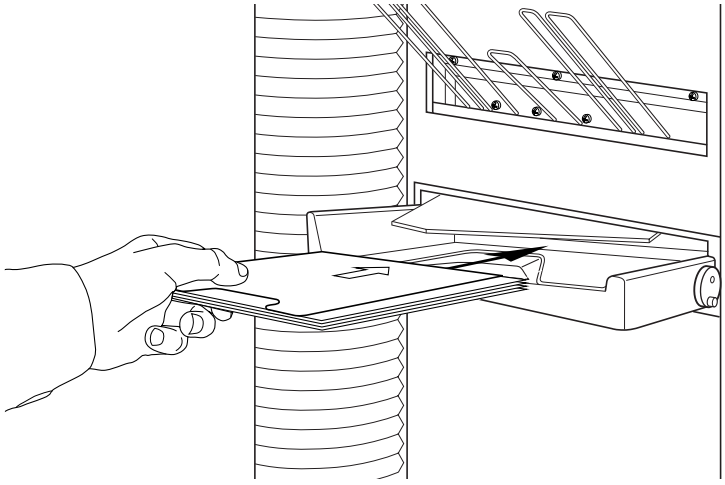
   You can arrange the films in any order, although you may wish to use a sequence defined by your site (for example, the four standard views first, followed by additional or equivalent views). As needed, turn films a quarter turn to match the orientation shown on the separator sheet.

   If you load films in a random order as shown below, you will have to reorient the images later via the Image Correction screen.



3. Load the stack into the input tray. Insert the stack with:
   - The arrow on the top separator sheet pointing into the scanner.
   - The leading edges of the films and separator sheets aligned flush.

You can load up to 100 sheets – including films and separator sheets.



Loading Films

4 Select the Any protocol by touching **Any**.

⚠ ***Note:*** *You cannot change the scanning protocol while a case is being scanned.*

5 Touch **Start**. The system status changes from 'Ready' to 'Scanning', and the **Start** button changes to **Stop**.

A new study icon appears at the top of the study list. As soon as the first film is scanned, the icon displays the yellow alert symbol. The case status shows 'Failed' with an explanation that the image contains an unknown view. After the entire case has been scanned, you must identify all image views via the Image Correction screen and reprocess the case. To do so:

6 Touch an image to display the Image Correction screen. See '3.9. Verifying Scanned Cases' for further information on reorienting and labeling images. Identify each image and correct the orientation as needed.

7 When done, touch **Reprocess** on the Image Correction screen to reprocess the images. The system returns to the Studies screen, and a white circle on the study icon flashes to indicate that the system is processing the views. When processing is complete, a white arrow on the icon flashes to indicate that the results are being transmitted to a display unit, printer, and/or archive system. Once the study has been transmitted, the icon appears solid green.

8 When the case has finished scanning, put the films and separator sheet together in the patient folder for hanging.

⚠ ***Note:*** *After scanning the case, the system returns to the default protocol configured on the Controls Scanning screen.*

3.6. Adding Cases to the Stack

You can add one or more cases anywhere in the stack. If you're not in a hurry for the case, add it to the bottom. If you're in a hurry, add it to the top. (Cases at the top are processed first.)

⚠ ***Note:*** *This procedure can produce an alert indicating there were too few films for the previous case. However, it is often faster to remove the films and produce the alert than to wait for the films to be scanned and processed.*

⚠ ***Important:*** *Verify that cases you add to the stack conform to the selected scanning protocol, or select the desired protocol before scanning the case.*

▶ **To add cases to the stack**

1. Prepare the cases to be scanned as described in '3.2. Preparing Cases to Be Scanned'.
2. If the system is currently scanning, touch **Stop**. The scanner will stop after it finishes the current film.

   ⚠ ***Important:*** *When you touch **Stop**, the system always resets to the default scanning protocol. If the system generates an alert, touch **OK** in the pop-up window.*
3. Remove the films and separator sheets from the feeder. Rebuild the stack in the order you want to run the cases. If you want to run the new cases first, add them at the top of the stack.

   ⚠ ***Note:*** *Be sure the films and separator sheets are in the correct order. If the system did not scan all the films from the last case, take the scanned films from the output tray and put them together with the films that were not scanned.*
4. Insert the new stack of cases into the feeder.
5. If necessary, select the scanning protocol you want to use.
6. Touch **Start** to resume scanning.

3.7. Stopping Scanning and Removing a Case

You cannot 'cancel' a study, but if you don't want to continue scanning the current set of films, you can stop the system and remove any remaining films from the input tray (as described below).

⚠ ***Note:*** *This procedure can cause the system to produce an alert indicating there were too few films. However, it is often faster to remove the films and produce the alert than to wait for the films to be scanned and processed.*

⚠ ***Important:*** *If you changed the scanning protocol from its default setting before you started scanning (e.g., if the default scanning protocol on the Controls Scanning screen is Auto and you touched* ***Screening*** *before touching* ***Start****), the system resets the scanning protocol to its default when you touch* ***Stop*** *in step 1 of the procedure below. If you want to resume scanning with the non-default protocol after removing one or more cases, you'll need to select that scanning protocol again before touching* ***Start*** *in step 6.*

▶ **To stop scanning**

1. Touch **Stop**. The scanner will stop after it finishes scanning the current film.

   ⚠ ***Note:*** *If the system generates an alert, touch OK in the pop-up window.*

2. Remove the entire stack from the input tray.
3. Remove the remaining films for the cancelled case.
4. As desired, remove any other case, that is, the separator sheet and the films associated with it.
5. Place the remaining cases back in the input tray.

   ⚠ ***Important!*** *Be sure that the next item to be scanned is the separator sheet for the next case.*

6. Select the desired scanning protocol, if not already selected.
7. Touch **Start** to resume scanning.

3.8. Viewing Study Information

As each study is processed, the system displays the study information on the Studies screen. The results include the image thumbnails, patient flash (if present), and patient information.

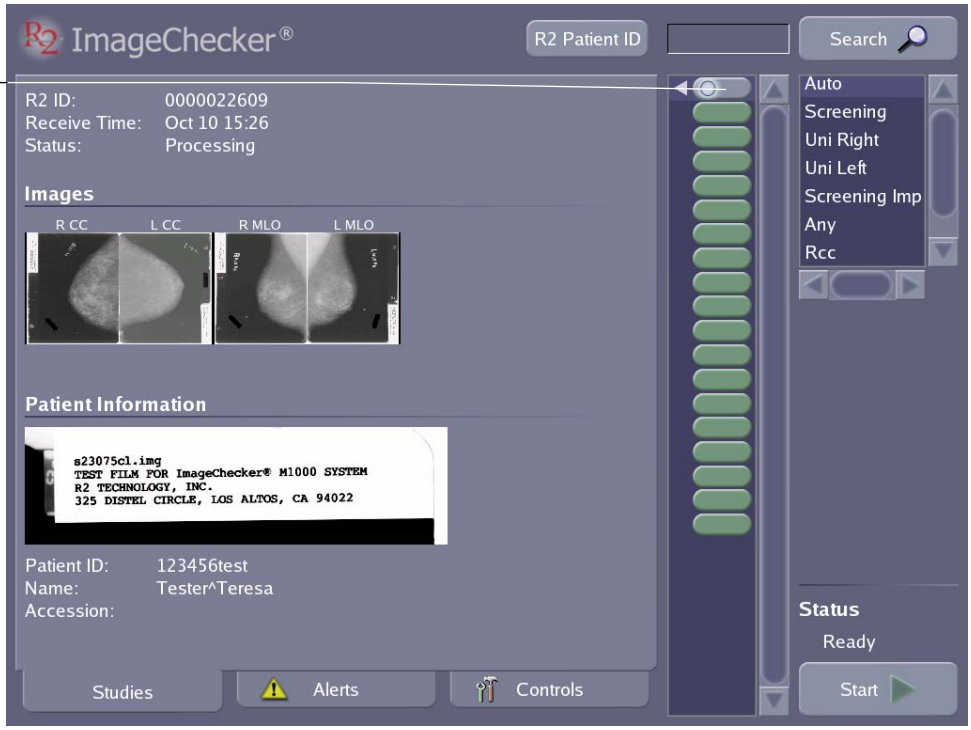
You can display study information in one of three ways:

- You can touch the study icon in the study list.
- You can type the patient identification, name, or R2 ID (separator sheet barcode number) and press ↵Enter (or touch **Search**).
- You can use the handheld barcode scanner to scan in the patient identification or R2 barcode number.

For more information about searching, see '3.12. Searching for a Study'.

The Study icon at the top represents the study currently being processed or the study most recently processed.

The Study icons below represent studies processed earlier.



For any scanned case, the system displays the following:

- The **R2 ID**, which is the barcode number from the study's separator sheet
- The **Receive Time**, which is the time film scanning began for the selected study.
- The study **Status**. Depending upon the case, the Status field can display a variety of messages (see table, next page).
- Thumbnail **Images** of films. These images appear as they are processed and can be viewed at any time after processing is complete. Touch any thumbnail image to open the Image Correction screen.
- **Patient Information** shows the patient flash from the scanned film (if present), followed by the Patient ID, Name, and Accession number from the reporting system or R2 Technology's patient identification system. The patient flash image appears for each film as it is scanned. After the system scans the last film for a

study, it retains the patient flash image from that film as part of the study information.

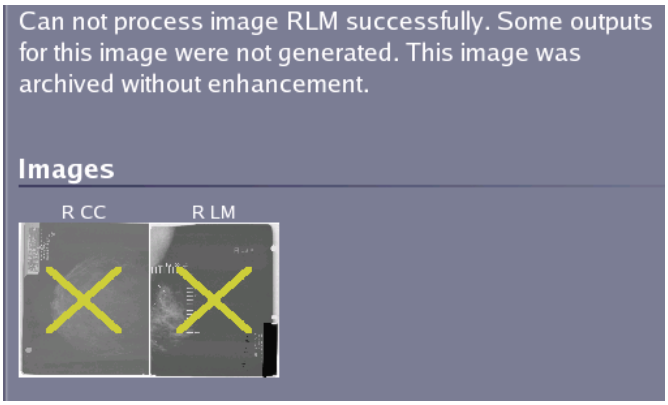
⚠ ***Note*** *the following:*

- *The image thumbnails always appear in film scanning order. Once the films have been scanned, you cannot change the order.*
- *The thumbnails are always shown in anatomic orientation (e.g., RCC nipple points left), and this orientation cannot be changed.*
- *CAD marks do not appear on the touch-screen monitor. The CAD marks appear only on the output devices (display units, review workstations, printouts, etc.).*

The following table shows the Status conditions that the system can display for a case.

Case Status Message	Meaning
Processing	The system is scanning and processing the selected case.
Needs Verification	The system requires you to review and 'verify' the case images before it will send the study results to a display device or archive.
Transmitting	The system is transmitting the scanned images to a display device or archive.
Completed	The system has finished transmitting the study.
Failed	The system was unable to complete the processing or study transfer and has issued an alert.

If one or more images in the study could not be processed for any reason, a yellow 'X' appears on the image. However, all scanned images will still be sent to the PACS if your system is configured for archiving. See 'Part 4: Alerts' for more information on alert messages.


Can not process image RLM successfully. Some outputs for this image were not generated. This image was archived without enhancement.
Images
R CC
R LM

⚠ ***Note:*** *The message shown in the example above indicates that the images were archived using Natural Pixel Values instead of in the DigitalNow ELC Enhanced MG image format. For more information, see 'Digital Image Output Options' on page 28.*

3.9. Verifying Scanned Cases

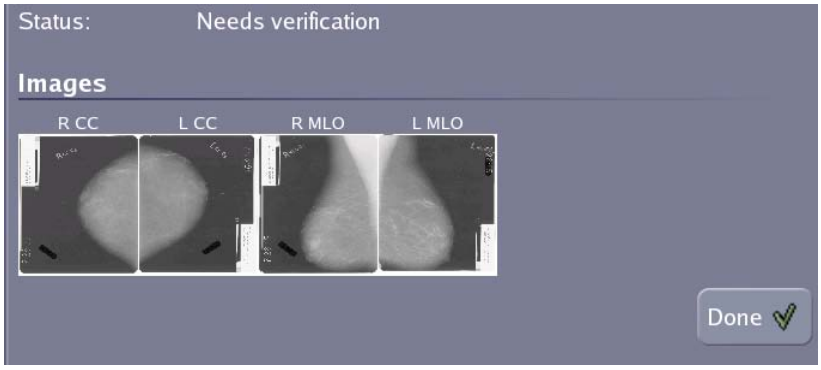
At some facilities, the system will require you to 'verify' scanned cases before you archive them. The verification step is configured by selecting the 'On with verification' setting on the Controls Outputs screen (see '5.4. Outputs Options').

⚠ ***Important!*** *Hologic|R2 recommends that facilities using DigitalNow DICOM Export always verify the images before archiving them to reduce the chance of improperly oriented or identified images being sent to PACS.*

If your system has been configured to require verification, then after the system processes the cases it displays a blinking question mark on each study icon. The question mark also appears on the Studies screen tab at the lower left of the screen.

▶ **To verify cases**

1. Touch the study icon for the case you want to verify. The system displays the results for the selected study.



2. Review the case results. Check to see that the images are oriented correctly and that patient was retrieved successfully from the archive.
3. Touch the Done button or make corrections.
   - If the results are acceptable, touch the Done button. In response, the system transmits the results to the archive or other output device.
   - If the results are not acceptable, or if the system produced an alert for the case, you may need to take corrective action. In some situations, you may need to reorient or label images by using the Image Correction screen. For more information, see '3.10. Correcting Scanned Images'.
4. Repeat these steps for each case needing verification.

3.10. Correcting Scanned Images

After you scan a case, you use the Image Correction screen to reorient images, change film view labels and modifiers, or add a DICOM study description. For example, you must correct the scanned images if a case includes one or more non-standard views or view modifiers, or if the system is unable to identify a lead marker. In addition, you must use the Image Correction screen for all cases scanned with the Any protocol.

In many cases, the system issues an alert to let you know that it could not completely process the case. However, you can use the Image Correction screen even with cases that have been completely processed without alerts.

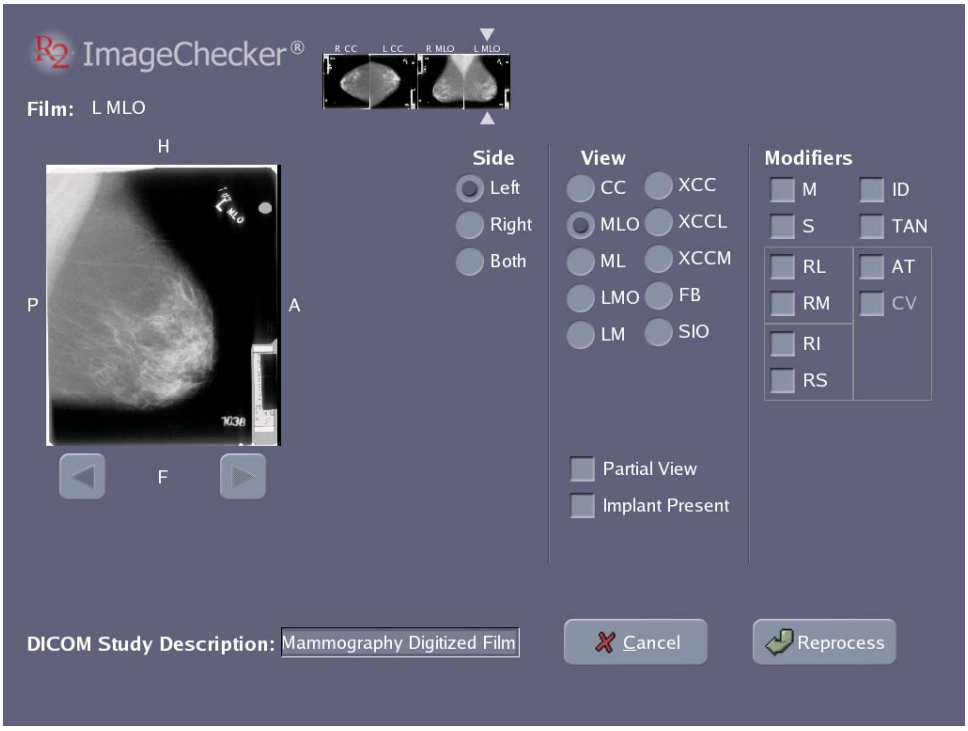
The Image Correction screen allows you to:

- Reorient scanned images (flip or rotate them)
- Change the film view labels and modifiers (e.g., RCC to LCC)
- Edit the DICOM study description for the case

⚠ ***Note:*** *If films for two or more patients were scanned under a single separator sheet, you must rescan the case.*

▶ **To correct scanned images**

1 **Open the Image Correction screen.** Touch the study icon for the study you want to work with. Then touch one of the thumbnail images. The Image Correction screen opens as shown in the following example:



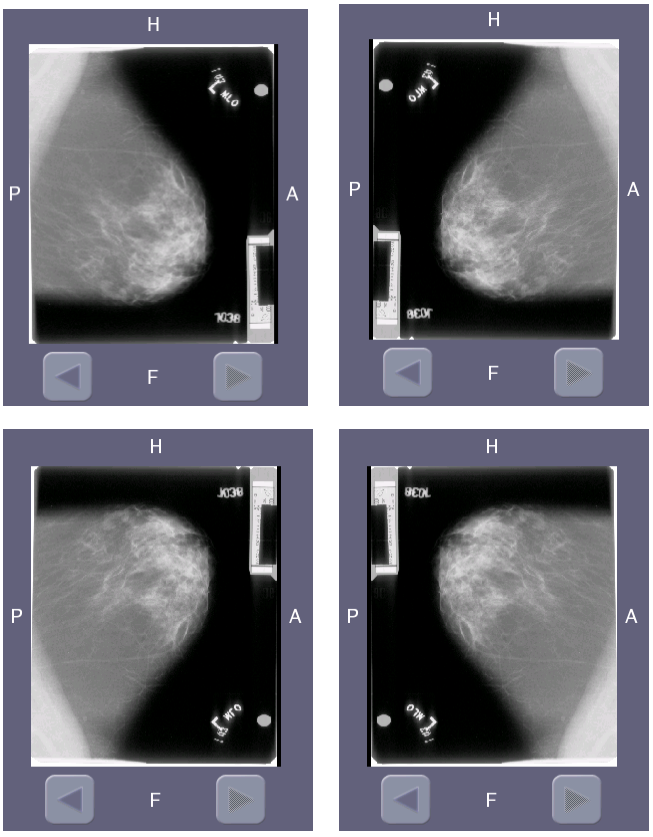
The image thumbnails for the case appear at the top of the screen. The image you selected appears enlarged at left. To navigate through the study images, touch the arrow buttons below the enlarged image, or touch any of the image thumbnails.

⚠ ***Note:*** *If the displayed images and their labels and DICOM Study Description are all correct, then simply touch Cancel to return to the Studies screen.*

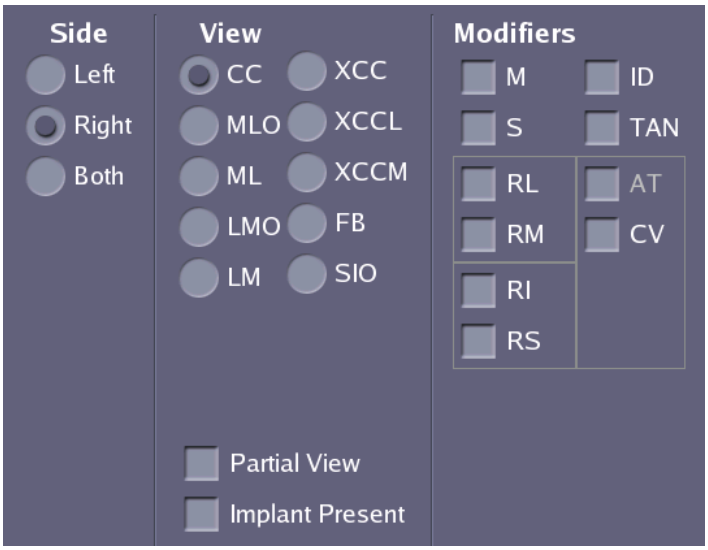
2 Reorient image, as needed.

a Touch the enlarged thumbnail at the left of the screen. Each time you touch the image, it flips alternately along the vertical and horizontal axes. Flipping the image a total of four times restores the original orientation.

b Check the image orientation with the indicators on the four sides of the image (Left, Right, Anterior, Posterior, Head, Foot). When the orientation is correct, go on to step **3**.



3 **Modify the view label, as needed.** To define or change the view label, build it from left to right: select a side, a view, and then modifiers (as needed).



a Touch the proper Side selection: **Left**, **Right**, or **Both** (for cleavage view).

b Touch the proper View selection. Note the two additional selections below the view area for Partial View and Implant Present.

c Touch to select Modifiers as needed.

As you build the view label, invalid selections are eliminated. For example, if you choose Both for the side, the system automatically sets the view to CC and the modifier to CV. You can chain valid modifiers together as needed.

Some modifiers (for example, M and S) appear before the view designation; other modifiers (such as ID and TAN) appear after the view designation.

⚠ ***Note:*** *You must select a view when using the TAN modifier, as TAN can be used with either the CC or MLO view.*

See 'CAD-Supported Views' on page 26 for a complete list of views and modifiers.

4 **Repeat steps 2 and 3 for each image.**

5 **Modify the DICOM study description, as needed.** If desired, touch the DICOM Study Description field and use the keyboard to change the DICOM study description for the case. The default description is 'R2 Mammography Digitized Film'.

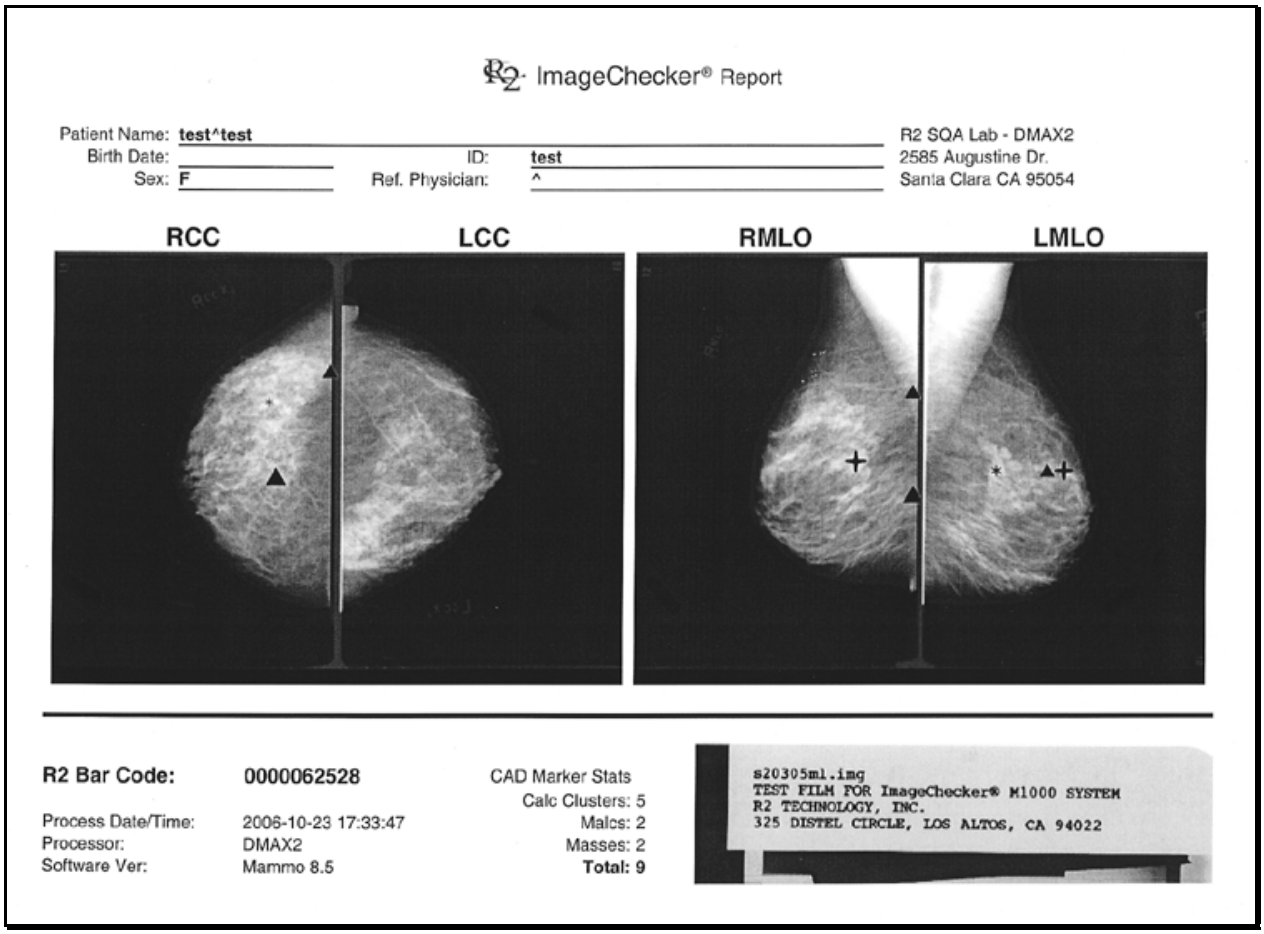
⚠ ***Note:*** *All images in the case will contain the same DICOM Study Description; modifying it in one image changes it for all images in the case.*

6 **Reprocess the case.** Once the images and their labels are correct, touch **Reprocess**. The system cancels the old case (removes the old study icon), reprocesses the case (all images), and creates a new study icon at the top of the study icon list. If the system does not issue an alert, it automatically sends the results to the output devices (PACS, display unit, printer, etc.).

3.11. Printing CAD Results

If you have configured the system to print CAD results for every study (as described in '5.7. Printing Options'), the CAD results are automatically printed when processing is complete.

The following is an example of a CAD Results Report:



If you want to create an additional paper printout of the CAD results, touch any of the thumbnail images for the case and reprocess it. Because the films are not rescanned, the results for the case will be identical to the original.

3.12. Searching for a Study

You can search for and display the information from any previously processed study using any of the following study data:

- R2 ID (from the separator sheet barcode)
- Patient ID (from the reporting system)
- Name (from the reporting system)

The search is limited to the 200 most recently processed studies (or fewer, depending on the available disk space in the processing unit's computer).

▶ To search for a study and display its results

1 **Type the data** for the study you want to find. You can just start typing; you don't need to touch the Search field first. You can also enter data by using the handheld scanner to scan a barcode from a patient record or separator sheet.

⚠ ***Note:*** *The system does not accept (or need) wildcard characters (e.g., *). The search function will find any data that partially or completely matches the text you enter. If you leave the search field blank, the search returns all studies on the system.*

2 Touch **Search**. The search results appear:

- If only one study matches the search criteria, the system displays the study information automatically.
- If multiple matches occur, the system displays the Search Results window, as shown in the following example.

⚠ ***Note:*** *To move the window, touch and drag the Search Results title bar.*

If more than one study appears, touch the study you want to see. The Search Results window closes and the results of the study you selected appear on the Studies tab.

3.13. Using Queue Manager

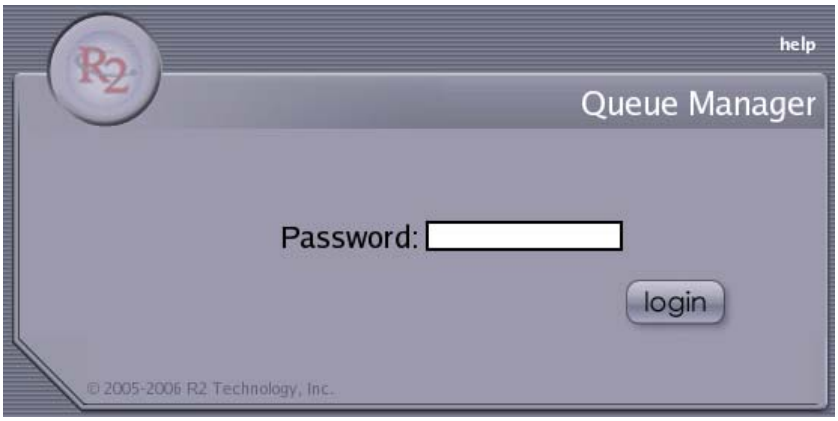
Queue Manager enables you to monitor and manage the queue of cases being processed by the R2 system.

▶ To enter Queue Manager

1 Using any web browser on the same network as the R2 system, in the Address box type the IP address for the processing unit followed by /qman, and press ↵Enter. For example:

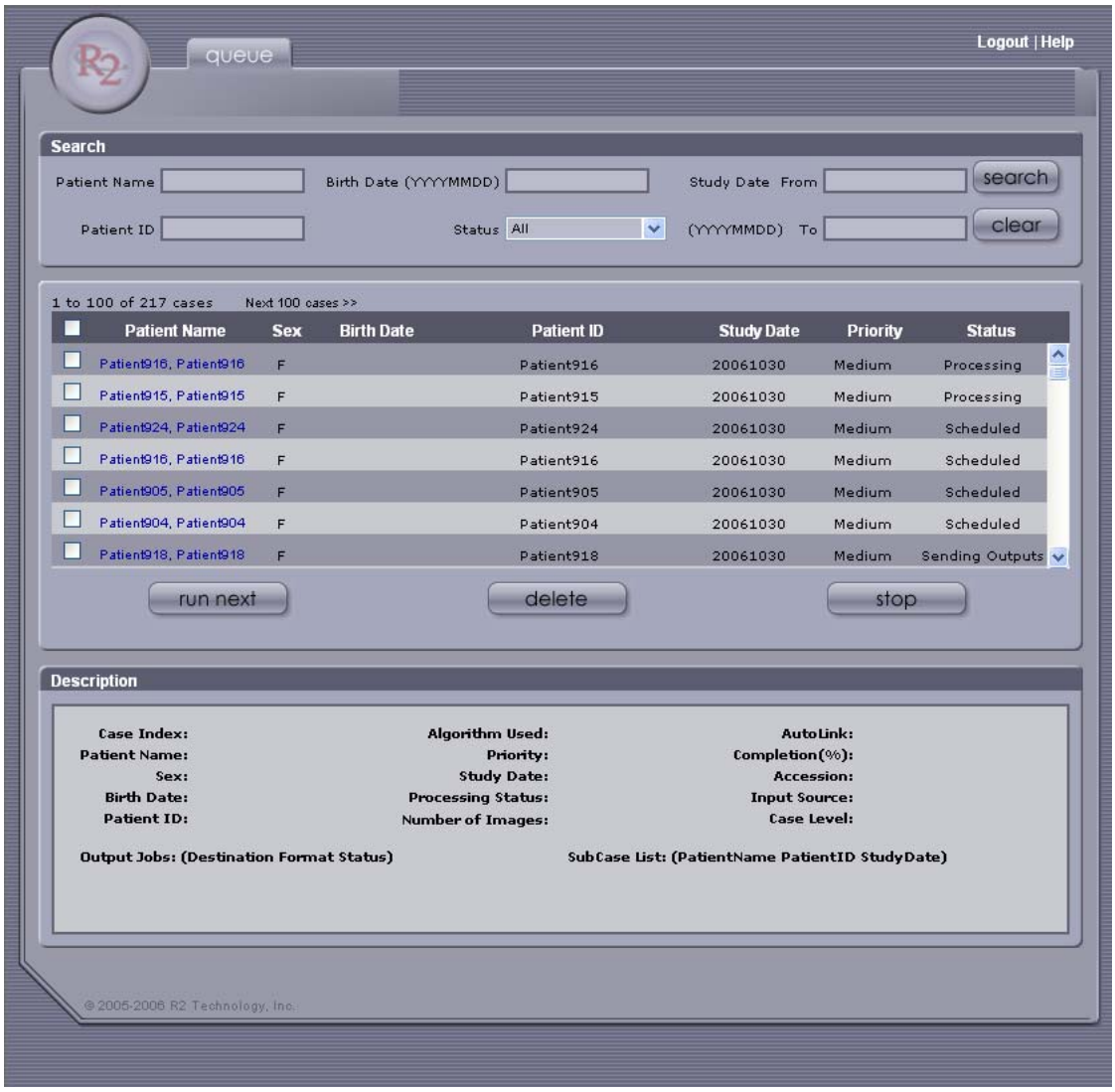
http://12.345.67.89/qman

The browser will display the log-in window.



2 Enter your Queue Manager database password (h0spital), and click login.

The system displays the Queue Manager screen, showing the list of cases and the status of each case. Click Help at the upper-right corner for detailed instructions.



- You can filter the list of cases by entering search criteria in any of the fields in the Search panel at the top of the screen and then clicking the search button.
- You can sort the list of cases by clicking on any of the column headers. Clicking it again reverses the sort order.
- When you click on a patient name, the information associated with the study is shown in the Description panel at the bottom of the screen.

3 Select one or more cases using the checkboxes on the left side of the queue.

4 Use the **run next**, **delete**, and **stop** buttons to move the selected case(s) to the top of the queue (run next), delete them, or stop processing them.

5 When you are finished, exit the web browser.

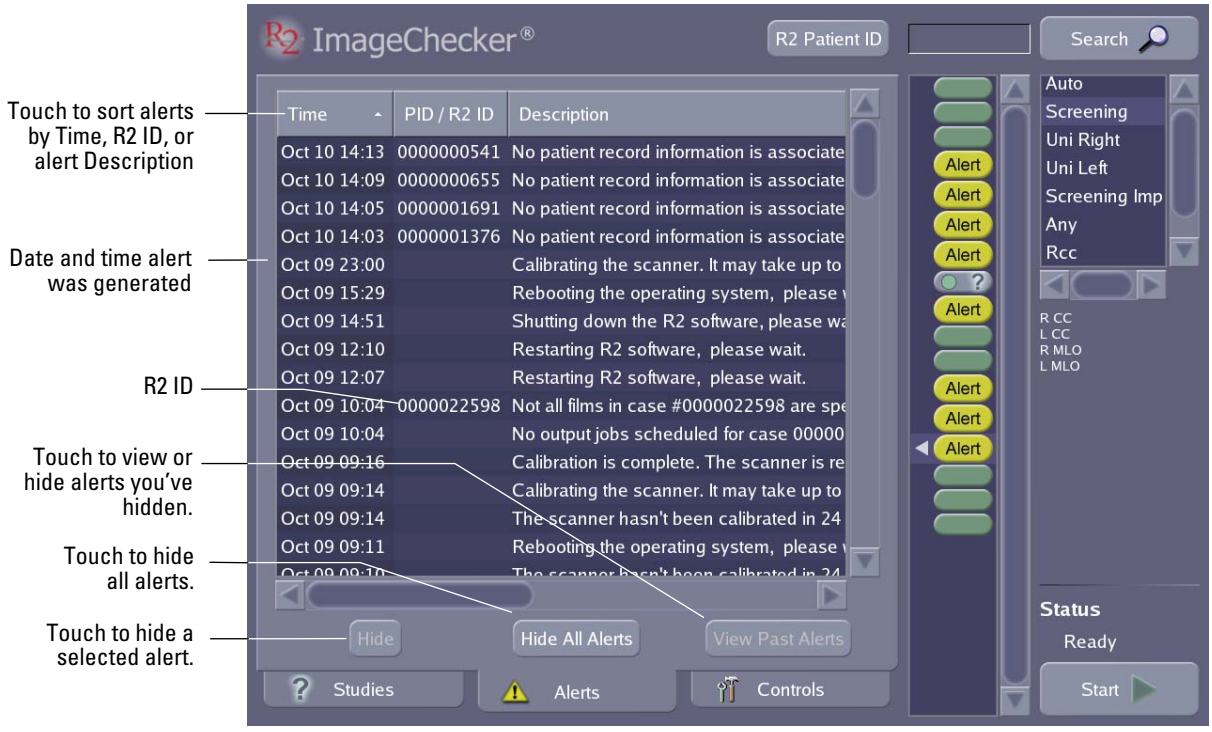
Part 4: Alerts

- 4.1. Alerts Listed Alphabetically
- 4.2. Common Questions

Part 4 provides a listing of alert conditions with instructions for resolving the alerts and diagnosing and solving common problems.

The Alerts are designed to help you and Hologic | R2 service personnel diagnose problems when they arise. When they occur, the alerts appear in two places:

- On the **Studies** screen, just below the Status field for the study currently displayed.
- On the **Alerts** screen, where you can view all recent alerts.


Touch to sort alerts by Time, R2 ID, or alert Description
Date and time alert was generated
R2 ID
Touch to view or hide alerts you've hidden.
Touch to hide all alerts.
Touch to hide a selected alert.
ImageChecker®
R2 Patient ID
Search
Time
PID / R2 ID
Description
Oct 10 14:13 0000000541 No patient record information is associate
Oct 10 14:09 0000000655 No patient record information is associate
Oct 10 14:05 0000001691 No patient record information is associate
Oct 10 14:03 0000001376 No patient record information is associate
Oct 09 23:00 Calibrating the scanner. It may take up to
Oct 09 15:29 Rebooting the operating system, please
Oct 09 14:51 Shutting down the R2 software, please wa
Oct 09 12:10 Restarting R2 software, please wait.
Oct 09 12:07 Restarting R2 software, please wait.
Oct 09 10:04 0000022598 Not all films in case #0000022598 are spe
Oct 09 10:04 No output jobs scheduled for case 00000
Oct 09 09:16 Calibration is complete. The scanner is re
Oct 09 09:14 Calibrating the scanner. It may take up to
Oct 09 09:14 The scanner hasn't been calibrated in 24
Oct 09 09:11 Rebooting the operating system, please
Alert
Auto
Screening
Uni Right
Uni Left
Screening Imp
Any
Rcc
R CC
L CC
R MLO
L MLO
Hide
Hide All Alerts
View Past Alerts
Status
Ready
Start
Studies
Alerts
Controls

Also, whenever the system generates a new alert, an alert icon (⚠) appears on the Alert tab.

4.1. Alerts Listed Alphabetically

The alert messages are presented here in alphabetical order, with instructions for addressing each problem.

Archiving was cancelled for case (3045)

The barcode has no associated patient information in the reporting system database.

Enter the patient information into the reporting system database, including the R2 barcode on the separator sheet scanned with the case, then reprocess the case via the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.

Cannot process image successfully (1063)

The system is unable to perform CAD processing or image enhancement on the image due to poor film quality. A yellow 'X' appears on the image thumbnails on the Studies tab. Even though no processing was possible, the scanned images are archived as usual.

- Verify that the images have the correct view labels, if not correct the view labels on the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.
- Verify that the image views and view modifiers are supported for CAD processing. See '2.6. System Inputs and Outputs' for more information.

Cannot process this case (1062)

The R2 software cannot work with the images as they are.

- Correct the images as necessary via the Image Correction screen, and reprocess the study.
- If films for two or more patients were scanned under a single separator sheet, rescan the case.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

Could not connect to reporting system database (3503)

The system is unable to retrieve a patient record from the reporting system. The reporting system may be off-line or the R2 system may not be set up properly to connect to the reporting system.

- Verify that the reporting system server is up and running.
- Check network cables to confirm that they are properly connected.
- Consult with the reporting system administrator at your facility.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker attempted but could not send case (3016, 3018, 3031, 3032)

The system is trying to transfer the images but cannot find the specified output device (display unit, PACS, etc.). The system will try repeatedly to send the images. Usually, it is either a display unit problem or your computer network is down. To fix:

- Make sure the display unit is up and running. If this was the problem, the studies should transfer within about ten minutes.

- If this isn't the problem, check to be sure all cables between the processing unit and the display unit are connected and that the computer network is up.
- If your network is up, all cables are connected, and the display unit is in working condition, call Hologic | R2 Technical Support.

ImageChecker attempted but could not print reimbursement report (2008)

The system has canceled the print request for the study. You will only see this alert after several 'Printer not found...' alerts. The system tries repeatedly to print and displays this message when it gives up. To fix:

- Verify that the printer is on, on-line, and has enough paper. After correcting any of these problems, ensure that printing is set to 'on' and reprocess the study in the Image Correction screen.
- If the 'Printer not found...' or similar alert appears again, check that all cables between the printer and the processing unit are connected. Check with your system administrator that your network is up. Reprocess the study in the Image Correction screen and print.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker cannot contact the scanner (1010)

This message may occur during system start-up, or if the scanner was inadvertently turned off. The system does not allow scanning films until the problem is fixed.

- If the system is rebooting, wait about 5 minutes.
- Power-cycle the system. See '6.3. Power-Cycling the System'.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker cannot identify the lead markers (3023)

This message appears when scanning with the Auto protocol. It means that the system did not recognize the lead markers. Either they are not one of the supported types or there is a problem with marker position and/or placement on the film(s). To fix:

- Identify and label the views on the Image Correction screen and reprocess the study. If this doesn't fix the problem, call Hologic | R2 Technical Support.

ImageChecker cannot read the barcode (1041)

The scanner is not able to read the barcode on the separator sheet.

- Ensure that the separator sheet is in the proper position (e.g., is not half-fed in the feeder) and is not damaged
- Reload the stack and restart scanning.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker is busy (3012, 1029, 1030)

The images for the study have not yet been sent.

- Wait about ten minutes – the problem should resolve itself.
- If it doesn't, ensure the destination (i.e., display unit or printer) is up and ready to receive images.

- Check that all cables between the processing unit and the destination are connected and that the network is up.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker license not found (1024)

This message means the system could not verify a valid license.

- Ensure that the license dongle is present and properly connected. If this does not solve the problem, call Hologic | R2 Technical Support.

ImageChecker could not print a CAD report (2007)

The system has canceled the print request for the study. You will only see this alert after several 'Printer not found...' alerts. The system tries repeatedly to print and displays this message when it gives up. To fix:

- Verify that the printer is on, on-line, and has enough paper. After correcting any of these problems, ensure that printing is set to 'on' and reprocess the study in the Image Correction screen.
- If the 'Printer not found...' or similar alert appears again, check that all cables between the printer and the processing unit are connected. Check with your system administrator that your network is up. Reprocess the study in the Image Correction screen and print.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

ImageChecker could not send results (2005)

The system has tried to send the results to the desired output destination, but the time limit to retry has expired without successfully sending the results.

- Reprocess the images via the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.
- If the problem persists, call Hologic | R2 Technical Support.

Images didn't transfer (1031)

Images couldn't be sent to the output device (display unit, PACS, etc.) and the transfer was canceled by the system. You will see this alert only after several 'ImageChecker … could not send case #...' alerts (#3016) have appeared. The system tries repeatedly to send the studies and displays this message when it gives up trying.

- Be sure the display unit is up and running.
- Check cable connections between the processing unit and the display unit (i.e., the network cable from the system to the wall and the display unit network cable to the wall). Reprocess the study in the Image Correction screen.
- If this doesn't fix the problem, ask your system administrator if the network is up.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

Image transfer was interrupted (3013)

The system is trying to transmit results but cannot find the specified output device (display unit, PACS, etc.). The system will try repeatedly to send the results. To fix:

- Make sure the destination device on. If this was the problem, the results should appear within about ten minutes.
- Check that all cables between the processing unit and the destination device are connected and that the network is up.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

Missing or invalid barcode at top of stack (1016)

The scanner cannot read the barcode at the top of the stack.

- Check that the separator sheet is oriented correctly in the scanner input tray. See diagram on separator sheet.
- If the separator sheet is oriented correctly and the problem persists, call Hologic | R2 Technical Support.

No output jobs scheduled for case (3054)

The R2 system was not configured with any output destinations for CAD results.

If your system is set up to output to the printer only verify that printing is turned on at the Controls screen. See '5.7. Printing Options' for more information

No patient record information is associated with barcode (3501)

This alert appears when you are using the mammography reporting system and attempting to transmit the study results. It means that there is no patient record in the reporting system database with that specific barcode. When this alert is issued, the results will not be archived. Although you can print the results for the study, any patient information in the reporting system will not be listed on the printout.

The images in the R2 system are linked to the patient record in the reporting system by the separator sheet barcode number (R2 ID). When you scan the films, the R2 system searches for the patient record in the reporting system database so it can acquire the patient information.

Always enter the R2 barcode number into the patient record in the reporting system database before you scan the films.

If there is no patient information associated with the R2 ID, you can either:

- Enter the information into the R2 Patient ID system and reprocess the case, or
- Enter the information into PenRad, MRS or MagView and reprocess the case (to requery from their database)

Not all films in case are specified by scanning protocol (3024)

There are more films in the case than defined by the selected scanning protocol. Identify the film views via the Image correction screen and reprocess. See 3.9. Verifying Scanned Cases for more information.

Printer not found (3014)

The processing unit is attempting to send the study results to the printer, but the printer is not responding. The printer may be unable to respond, or there may be a network or configuration problem. The system will continue to try to send the study results.

- Verify that the printer is running.
- Check all cable connections between the processing unit and the printer (i.e., the network cable from the processing unit to the wall and the printer network cable to the wall). Sometimes a cable becomes loose. If so, wait about ten minutes, the system will resend the study results.
- Ask your system administrator if the network is down. If it is, and it is down long enough, the system will finally give up, and you will have to reprocess the study with printing turned on.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

Rebooting the operating system, please wait (5021)

You'll see this message when the system is rebooting (starting up again after being shut down and turned off).

- Wait about 10 minutes. Once the system comes back up, you will see the Ready message above the Start button.
- If the system doesn't come back up after 15 minutes, call Hologic | R2 Technical Support.

Reporting system query error (3502)

The R2 system could not communicate with the reporting system database, and possibly the system is not set up correctly. Contact Hologic | R2 Technical Support and they will diagnose and fix the problem.

Restarting R2 software, please wait (5019)

- Wait about 10 minutes. Once the system comes back up, you will see the 'Ready' message above the Start button.
- If the system doesn't come back up after 15 minutes, call Hologic | R2 Technical Support.

Scanner lock lever is raised (3051)

This usually happens when there are too many films in the feeder. Remove cases and touch OK to continue.

Scanner not ready! (5002)

For some reason, the scanner did not turn on properly.

- Power-cycle the system. See '6.3. Power-Cycling the System'.
- If this doesn't fix the problem, call Hologic | R2 Technical Support.

Scanner test failed (3025)

This message appears when you run the weekly test films and the scanner test fails. Usually you can clear the alert by rerunning ALL tests again.

- First, make sure the test films and separator sheets are not bent or damaged in any way. If they are, call Hologic | R2 Technical Support for replacements.
- Rerun all test films. See '6.4. Running the Weekly Tests'. Usually, this fixes the problem.

- If any tests fail again, power-cycle the system (see '6.3. Power-Cycling the System') and rerun the tests again.
- If any tests fail at this point, call Hologic | R2 Technical Support. Hologic | R2 does not recommend that you use the system if any of the tests failed.

Scanning is disabled, remote maintenance in progress (5010, 5059)

Hologic | R2 Technical Support is working on your system, and you'll need to wait until they are done.

- Wait two minutes. The Ready message will appear above the Start button.
- If your Hologic | R2 Technical support is done and the message does not go away, power-cycle the system. See '6.3. Power-Cycling the System'.
- If this doesn't fix the problem, call Hologic | R2 Technical Support.

Scheduled reimbursement report (5050)

Appears when the system prints a reimbursement report automatically (weekly or monthly, depending upon the system configuration). This is normal. The message does not appear when you print a reimbursement report manually. See '5.7. Printing Options' for more information.

Shutting down the operating system, please wait (5020)

This means the system is shutting down.

- Let the system shut down. Usually, it shuts down only when instructed to do so.
- If this happened on its own, power-cycle the system to bring the system back up. See '6.3. Power-Cycling the System'.
- If the alert continues to appear, contact Hologic | R2 Technical Support.

Shutting down the R2 software, please wait (5018)

This means the system is shutting down. It will shut down the R2 Technology software, then the operating system.

- Let the system shut down. Usually, it shuts down only when instructed to do so.
- If this happened on its own, power-cycle the system to bring the system back up. See '6.3. Power-Cycling the System'.
- If it happens again, contact Hologic | R2 Technical Support.

The same barcode has been assigned to multiple patients (3500)

This alert appears when you are using the mammography reporting system. It means you assigned the same R2 Technology barcode number to two different patients within the reporting system.

The images in the R2 system are associated to the patient record in the reporting system by the barcode number on the separator sheet. When you scan the studies, the R2 system searches for the patient record in the reporting system database that has that barcode and associates the images to that patient record. If there is more than one patient record with the same barcode, the system does not know which patient the images belong to.

- Access the reporting system database and check the patient records.
- Replace the duplicate barcode number with a new barcode number. Use this new sheet to scan the case.

The scanner is not responding (1007)

The internal scanner software is not responding to signals from the processing unit. By power-cycling the system, you can reset the internal scanner software.

- Power-cycle the system. See '6.3. Power-Cycling the System'.
- If this doesn't fix the problem, call Hologic | R2 Technical Support.

The scanner might be empty (3033)

The scanner is not detecting any films in the scanner.

- Ensure that the films and separator sheets are properly loaded (e.g., are not half fed in the feeder).
- Reload the case and restart scanning.
- If these steps do not solve the problem, call Hologic | R2 Technical Support.

X films were found when Y were expected. (1017, 1018)

This usually happens when (1) a separator sheet is missing from the stack or is upside down, (2) the system failed to read the barcode for the next case in the stack (the barcode is obscured, smudged, or damaged), or (3) a case did not have the number of films specified by protocol.

- Check to see if the next case is missing its separator sheet or if the barcode is obscured somehow. Add a separator sheet, or clean the separator sheet. If films for two or more patients were scanned under a single separator sheet, rescan the case.
- In many situations, you can simply correct the image labels and reprocess the images via the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.
- If these steps do not fix the problem, call Hologic | R2 Technical Support.

4.2. Common Questions

This Section provides common issues and solutions for R2 systems.

CAD does not run on views with implants

CAD does not run on images with the Implant Present modifier enabled, even if Implant Displaced is also enabled. If it is necessary to run CAD on Implant Displaced images, do not enable the Implant Present modifier either on the Image Correction screen or in scanning protocols.

CAD marks do not appear on thumbnails

Marks do not display on the thumbnails. They only appear on the display unit, print out, and/or archive system (if configured).

Case icons become yellow alerts; there are no images

Typically, an alert will be generated when an image fails to process. If it did, follow the instructions in the alert, or turn to the Alerts tab and look for that alert.

If an alert did not pop up, and there are no alerts in the Alerts screen, rescan the case using the appropriate Manual scanning protocol.

Film is 'missing' inside the scanner

If a film jams in the scanner, see 'Ejecting Films' on page 74.

Image is missing from a case

Occasionally, the film scanner reads the separator sheet barcode *through* the last film of a case. Although extremely rare, this can result in a case where the last image is missing. Sometimes an alert will appear ('X films were found when Y were expected'), but not always. This situation is most likely to occur with an LMLO image from a film with a light pectoral muscle, or with any film that has an extremely light area in the upper-left corner.

If you suspect that the film scanner has read a separator sheet barcode through a film, then reorient the film and rescan the case. As an alternative, run the case at the bottom of the next stack of cases.

Images are reversed in the thumbnails

Typically, this happens either when you are scanning with a Manual protocol and did not stack the films in the order expected by the R2 system or when you are scanning with the Auto protocol and the lead markers are bad or obscured.

- Use the Image Correction screen to flip the images to the correct orientation and reprocess. See '3.9. Verifying Scanned Cases'.
- If the problem persists, contact Hologic | R2 Technical Support.

Images at PACS/workstation are of poor quality

Contact Hologic | R2 Technical Support. In some cases, a service representative may need to adjust the contrast and brightness settings for your system. Also note that some DigitalNow ELC Enhanced MG images will not be rendered well, in particular, if (1) a film is very dark, (2) a normal-view image has a large, bright artifact, or (3) a

special-view image has a very dense region (i.e., as bright as regions with implants elsewhere in the image).

Images didn't print out

- Make sure the study processed successfully, or that there were no printer alerts. If a case did not scan and/or process successfully, it will not print out.
- If the system couldn't find the printer, it will generate an alert. To find out if there was an alert, check the Alerts screen.
- If the study processed correctly, check to make sure that printing is enabled. See 'Configuring CAD Results Printing' on page 76 for information on turning printing on/off. If printing is turned off, turn it on and reprocess the study in the Image Correction screen.
- If none of these steps fixes the problem, contact Hologic | R2 Technical Support.

⚠ ***Note:*** *As of version 8.5, not all scanned images are printed. Only four images appear on the printout. Images which have not been processed by CAD, and reversed views do not print.*

Images do not appear on my display unit

Typically, this happens when there is a delay on the processing unit.

- Check the processing unit for alerts.
- If there were no alerts, wait ten minutes, check the display unit again.
- Ask your system administrator if there have been network problems.
- If after ten minutes the images don't display and your network is up, contact your Hologic | R2 Service Representative.

⚠ ***Note:*** *R2 display units do not display all scanned images. For more information, see '2.6. System Inputs and Outputs'.*

Monitor isn't working

The monitor power switch may have been accidentally turned off. The processor unit is probably still working. Switch the monitor back on. If this doesn't work, verify that the monitor power cable is securely fastened.

Main screen is frozen and I can't do anything

Contact Hologic | R2 Technical Support. They will log in remotely and troubleshoot the system. DO NOT just turn off the system; if you do, you will not allow the software to shut down properly, which can result in other problems.

Patient ID flash on the printout is backwards

- Typically, this happens when you scan the case with a Manual protocol and loaded the stack or case upside down. See '3.9. Verifying Scanned Cases' for instructions on adjusting the image orientation.
- This problem can also occur if the service configuration is incorrect. If the problem persists, contact Hologic | R2 Technical Service.

Radiologist needs CAD quickly

For sites that archive images to PACS, a radiologist may request a quick turnaround for CAD results from certain films without waiting for the system to scan all films. Splitting the films into two cases may be undesirable because that produces separate studies at the PACS for the case. In such a situation, you can turn off archiving (see 5.4. Outputs Options), scan and process the requested views, and print the results for the radiologist. Then, turn archiving back on, scan and process all films for the case, and send the all results for the case to the PACS.

Scanned case before entering patient information

You can enter the patient information after scanning and reprocess the study to link the images to the proper patient. You must include the barcode from the separator sheet.

- See 'Part 7: Using DigitalNow and the R2 Patient ID System' for more information on entering patient information.
- See '3.9. Verifying Scanned Cases' for information on reprocessing a study.

Yellow 'X' appears on my image thumbnails

The yellow 'X' icon indicates that CAD processing could not be performed on an image.

- Verify that the images have the correct view labels. If they do not, correct the view labels on the Image Correction screen. See '3.9. Verifying Scanned Cases' for more information.
- Verify that the image views and view modifiers are supported for CAD processing. See '2.6. System Inputs and Outputs' for more information.

Even though no processing was possible, the scanned images are archived as usual.

Part 5: Controls

- 5.1. About Option
- 5.2. Maintenance Options
- 5.3. Shutdown and Reboot Options
- 5.4. Outputs Options
- 5.5. Patient ID Option
- 5.6. Performance Options
- 5.7. Printing Options
- 5.8. Scanning Protocols
- 5.9. Service Utilities

Part 5 provides instructions for using the system configuration and maintenance options that appear on the **Controls** screen. The **Controls** screen is used to configure system settings to meet your particular needs, run maintenance utilities, and display system information.

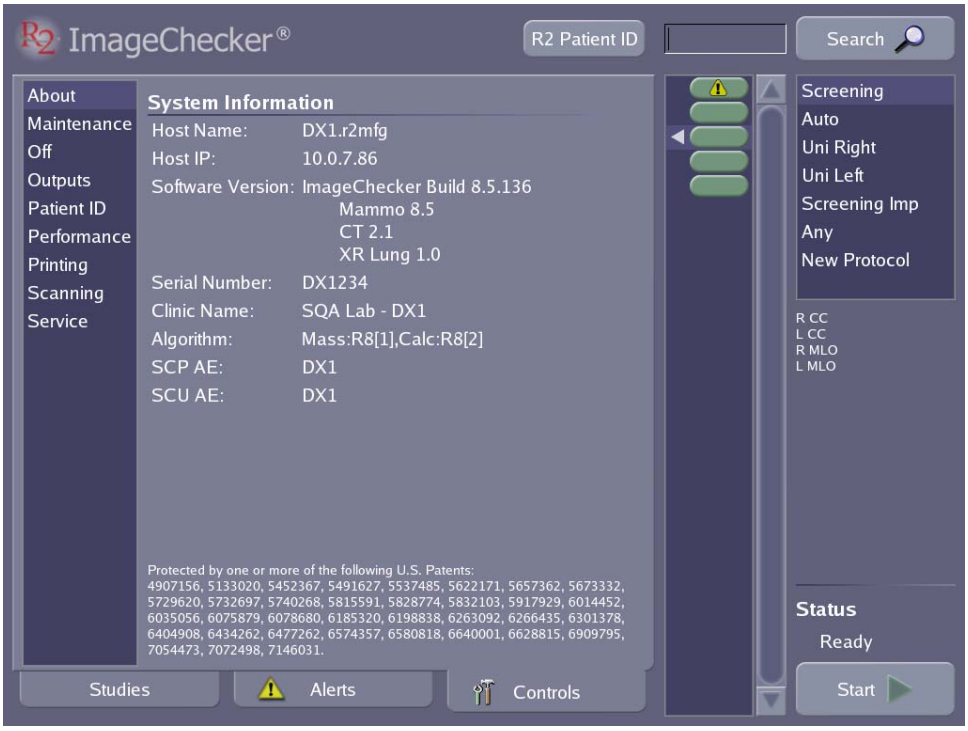
⚠ ***Note:*** *The* ***Outputs***, ***Patient ID***, *and* ***Printing*** *options appear only if they were configured by the Hologic|R2 service engineer when the system was installed.*

5.1. About Option

The About option on the Controls screen displays information about the configuration of your R2 film-scanning system on the network. This information is configured by service personnel when the system is installed. Normally, you will not need to refer to this information.

▶ **To display the About screen**

Touch the **Controls** tab and then select **About** (if the About screen does not appear).



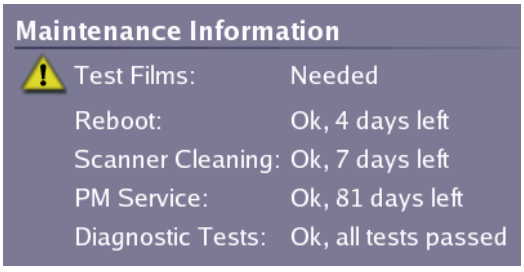
5.2. Maintenance Options

The Maintenance option on the Controls screen allows you to review whether scheduled maintenance is needed.

▶ **To display the Maintenance screen**

Touch the **Controls** tab and then select **Maintenance**.

The screen identifies any required maintenance procedures with a yellow alert icon. For further information, see 'Part 6: Maintenance'.


Maintenance Information
Test Films: Needed
Reboot: Ok, 4 days left
Scanner Cleaning: Ok, 7 days left
PM Service: Ok, 81 days left
Diagnostic Tests: Ok, all tests passed

5.3. Shutdown and Reboot Options

The Off option on the Controls screen allows you to:

- Reboot (restart) the system
- Shut down the system

▶ **To display the Off screen**

Touch the **Controls** tab and then select **Off**.

Use the Shutdown option whenever you need to power-cycle the system. Normally, you will shut the system down on a weekly basis and sometimes during trouble-shooting. For further information, see '6.3. Power-Cycling the System'.

When you touch Reboot or Shutdown, a confirmation window appears which requires you to either confirm or cancel the power down command.

5.4. Outputs Options

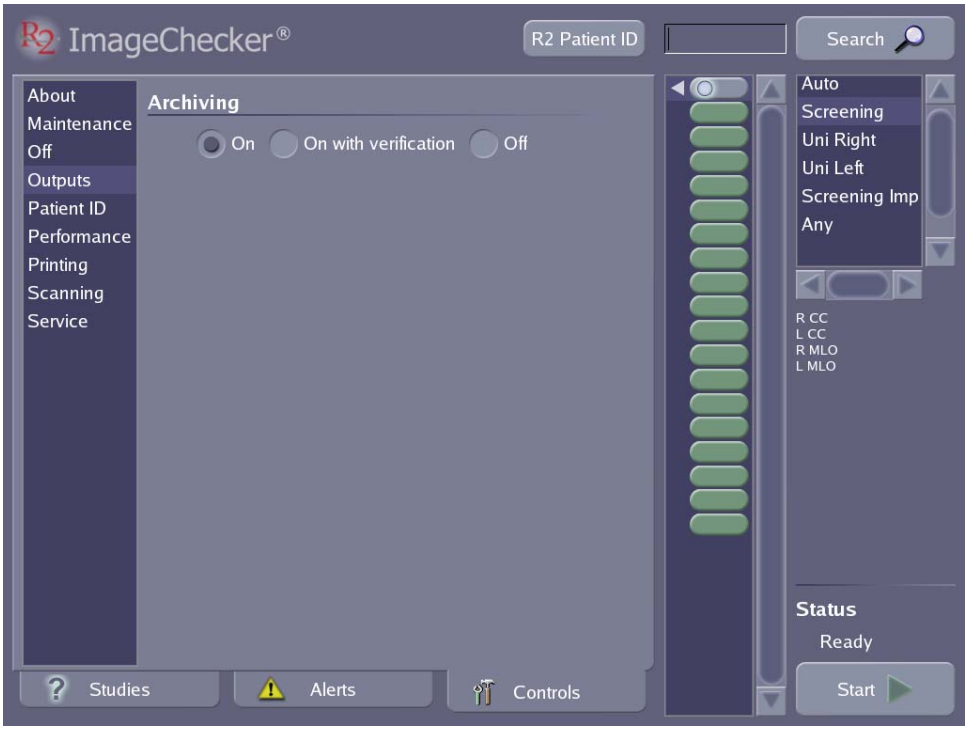
The Outputs option on the Controls screen allows you to specify whether you want R2 Technology's archiving feature turned on.

⚠ ***Note:*** *This option appears only if it was configured by the Hologic | R2 service engineer when the system was installed.*

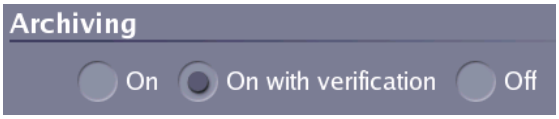
In order for Patient ID and Archiving to function, first a Hologic | R2 service engineer must configure your system to communicate to a patient database and the external storage provider (i.e., archive), respectively. The Archiving settings are available only when this feature has been licensed and properly configured on your system.

▶ **To display the Outputs screen**

Touch the **Controls** tab and then select **Outputs**.



- To enable or disable this feature, touch **On** or **Off**, as desired.
- To verify each study before it is archived, touch **On with verification**.



⚠ ***Important:*** *Archiving will function only if the reporting system is licensed and configured properly.*

⚠ ***Note:*** *Switching Archiving to 'On' has no effect on studies currently waiting to be verified. You must still manually verify each case.*

5.5. Patient ID Option

The Patient ID option on the Controls screen allows you to specify whether the R2 system should retrieve patient information from your reporting system or patient information database. If set up properly, when you scan the R2 ID, the R2 system will request that the reporting system transmit the patient information associated with the case. This option only appears if your site has licensed the reporting system integration feature.

A Hologic | R2 service engineer must first configure the R2 system to communicate with the reporting system. Once configured, you can enable or disable the data transfer using the Retrieve Patient Information setting on the Patient ID screen.

To enable or disable this feature, simply touch On or Off, as desired.

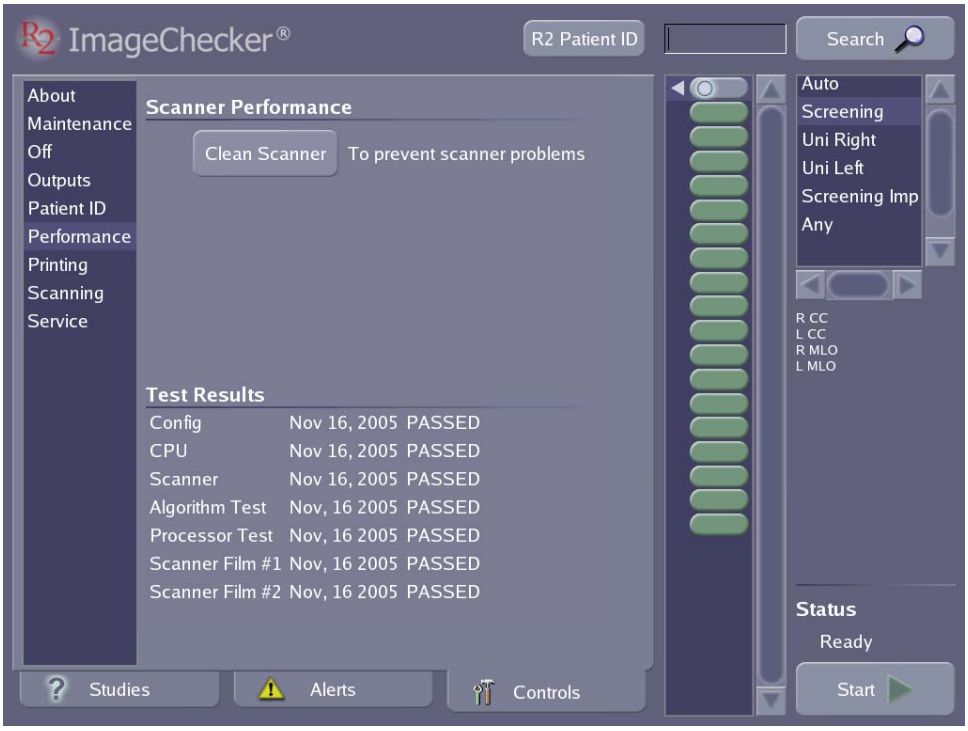
5.6. Performance Options

The Performance option on the Controls screen provides access to the:

- Film ejection procedure
- Scanner cleaning procedure
- Results of system verification testing

▶ **To display the Performance screen**

Touch the **Controls** tab and then select **Performance**.



Ejecting Films

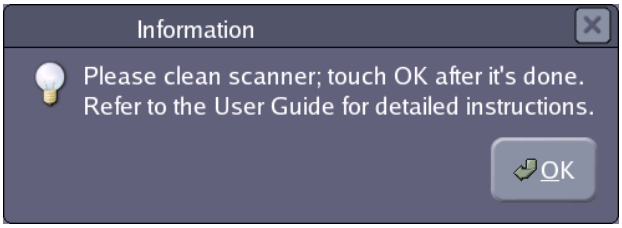
Use the following procedure if a film seems to be jammed inside the scanner.

▶ **To remove a jammed film**

1. Lift up the interlock (the protective shield on the input tray). If you can see the film, gently pull it out, using both hands and pulling gently but firmly.
2. If you can't see the film, or can't get it out, lift up the scanner control panel cover. Press the UP and DOWN arrows at the same time and hold them down for 3 seconds. The film should come out.
3. If the preceding step doesn't eject the film, power-cycle the system. See '6.3. Power-Cycling the System'.
4. If the preceding steps do not fix the problem, call Hologic | R2 Technical Support.

Resetting the Clean Scanner Timer

When you touch the **Clean Scanner** button, the system displays:



Clean the scanner as instructed in 'Part 6: Maintenance'. When you finish cleaning the scanner, touch the **OK** button shown above. When you touch **OK**, the Scanner Cleaning message on the Maintenance screen changes from 'Needed' to 'OK'.

If you do not clean the scanner, touch the 'X' shown above to cancel the timer reset.

Reviewing System Verification Results

The Test Results portion of the Performance screen provides the results of the most recent system verification testing, including the scanner test.

Test Results		
CPU	Nov 29, 2006	PASSED
Scanner	Nov 29, 2006	PASSED
Algorithm Test	Nov, 29 2006	PASSED
Processor Test	Nov, 29 2006	PASSED
Scanner Film #1	Nov, 29 2006	PASSED
Scanner Film #2	Nov, 29 2006	FAILED

For more information on the tests, see '6.4. Running the Weekly Tests'.

5.7. Printing Options

The Printing option on the Controls screen allows you to:

- Configure the system to send images and CAD results to a printer on your network. See 'Configuring CAD Results Printing' on page 76.
- Configure the system to print the barcode reimbursement report on a weekly or monthly basis (or not at all).
- Print the barcode reimbursement report. See 'Setting When the Reimbursement Barcode Report will be Printed' on page 76.

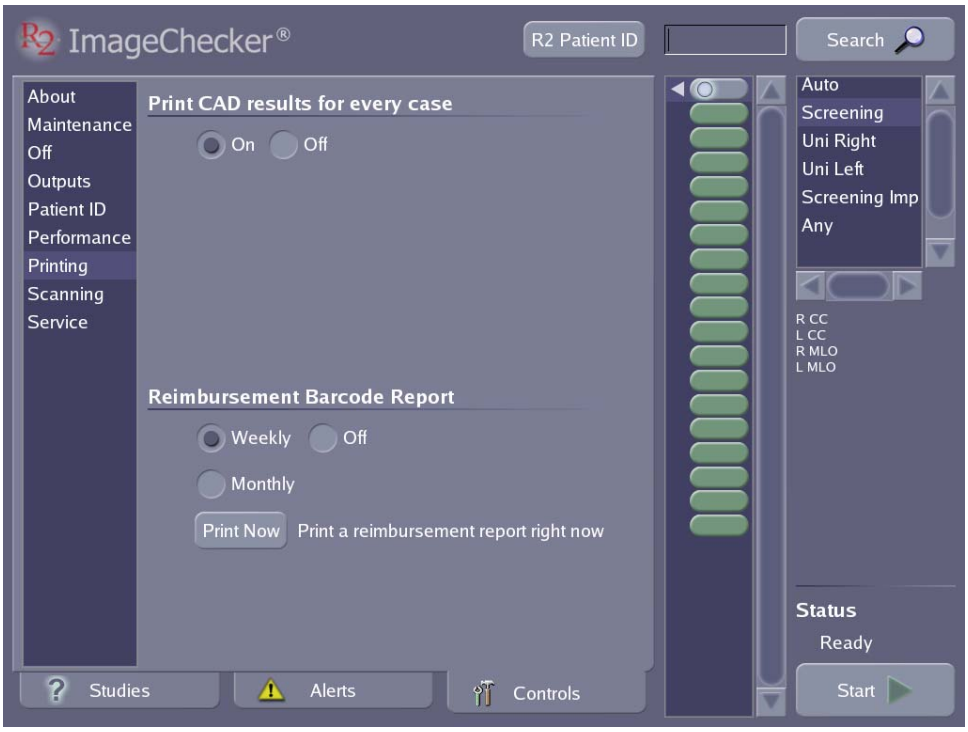
⚠ ***Note:*** *Printing options appear only if configured by the Hologic|R2 service engineer when the system was installed.*

⚠ ***Note:*** *Not all scanned images are sent to the printer. For more information, see '2.6. System Inputs and Outputs'.*

Once configured, you can use this screen to decide how you want to use the printer.

▶ **To display the Printing screen**

Touch the **Controls** tab and then select **Printing**.

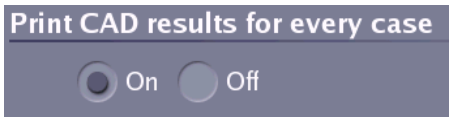


Configuring CAD Results Printing

You can configure the system so that it

- Prints images with CAD results for every case, or
- Does not print at all.

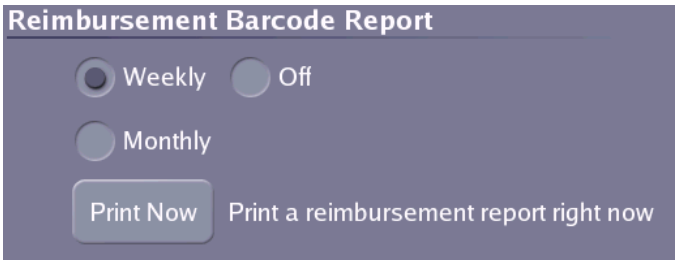
To enable or disable this feature, touch **On** or **Off**, as desired.



Setting When the Reimbursement Barcode Report will be Printed

You can choose to print a Reimbursement Barcode Report either automatically on a weekly or monthly basis, or not at all.

- To specify automatic printing of the reimbursement report, touch **Weekly** or **Monthly**.
- To disable automatic printing of the reimbursement report, touch **Off**.

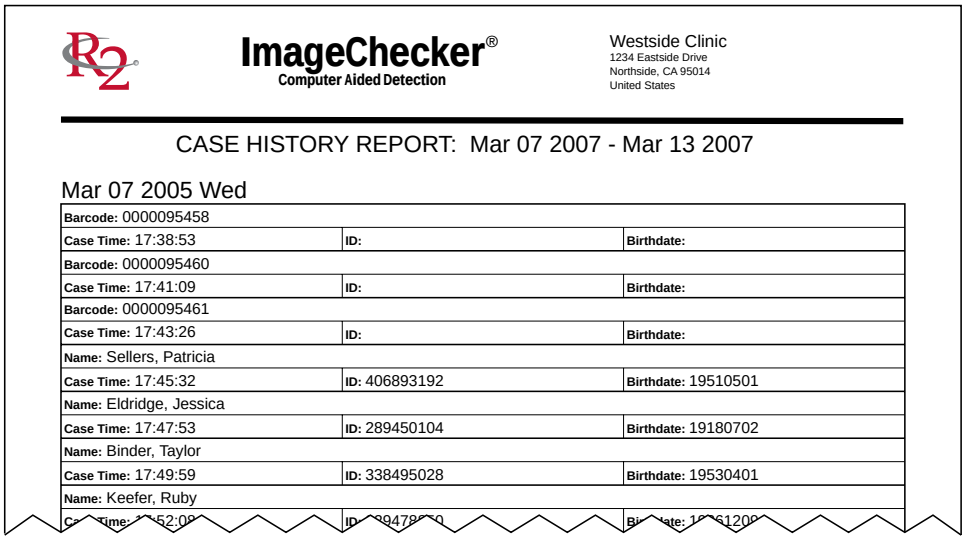


Printing a Reimbursement Barcode Report

▶ **To print a reimbursement report**

1. Touch **Print Now**. A calendar window appears.
2. Specify the date range and touch **Print**.

An example of a Reimbursement Report is shown below. The clinic information in the header can be configured by a Hologic | R2 service engineer. For each case, the report prints the R2 ID from the separator sheet, or the patient information, if the system was able to retrieve the patient information from the reporting system.



ImageChecker®
Computer Aided Detection

Westside Clinic
1234 Eastside Drive
Northside, CA 95014
United States

CASE HISTORY REPORT: Mar 07 2007 - Mar 13 2007

Mar 07 2005 Wed

Barcode: 0000095458		
Case Time: 17:38:53	**ID:**	**Birthdate:**
Barcode: 0000095460		
Case Time: 17:41:09	**ID:**	**Birthdate:**
Barcode: 0000095461		
Case Time: 17:43:26	**ID:**	**Birthdate:**
Name: Sellers, Patricia		
Case Time: 17:45:32	**ID:** 406893192	**Birthdate:** 19510501
Name: Eldridge, Jessica		
Case Time: 17:47:53	**ID:** 289450104	**Birthdate:** 19180702
Name: Binder, Taylor		
Case Time: 17:49:59	**ID:** 338495028	**Birthdate:** 19530401
Name: Keefer, Ruby		
Case Time: 17:52:09	**ID:** 294780150	**Birthdate:** 19361209

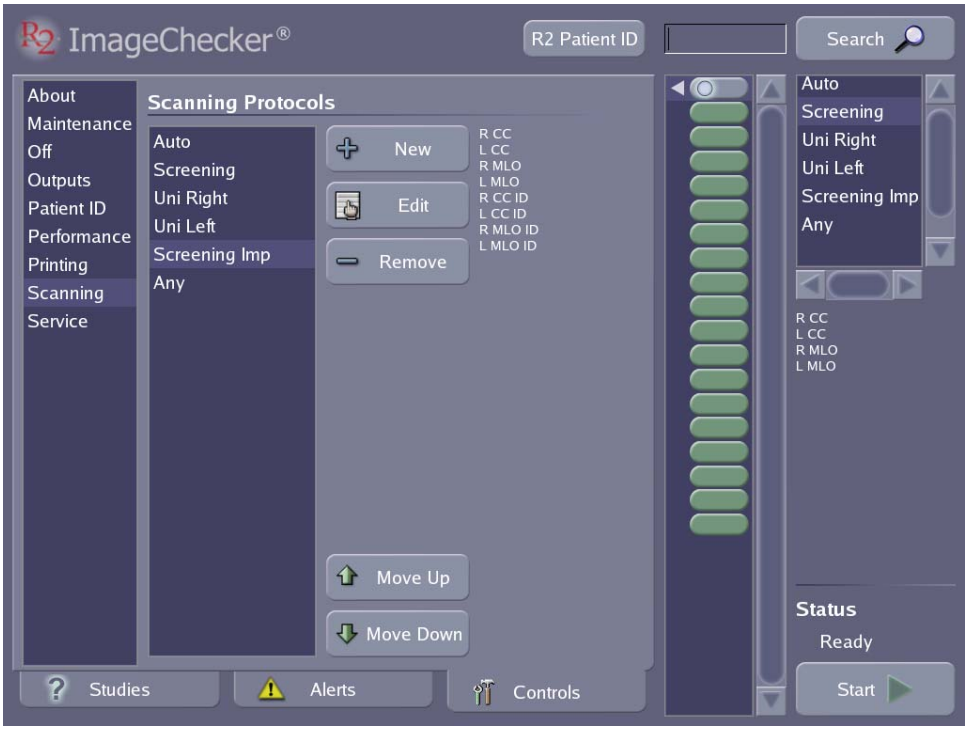
5.8. Scanning Protocols

The Scanning option allows you to perform the following procedures:

- 'Changing Scanning Protocol Order' on page 79
- 'Changing the Default Scanning Protocol' on page 79
- 'Deleting a Scanning Protocol' on page 79
- 'Creating Scanning Protocols' on page 80
- 'Editing Scanning Protocols' on page 81

▶ **To display the Scanning screen**

Touch the **Controls** tab and then select **Scanning**.



Changing Scanning Protocol Order

You can change the order in which the scanning protocols appear in the scanning protocol list on the Studies screen.

▶ **To change the scanning protocol order**

1. Touch a scanning protocol in the list at the left of the screen.
2. Touch the **Move Up** and **Move Down** buttons to move the selected scanning protocol up or down in the list.

Changing the Default Scanning Protocol

The default scanning protocol appears at the top of the scanning protocol list.

▶ **To change the default scanning protocol**

1. Touch the desired default scanning protocol in the list at the left of the screen.
2. Touch the **Move Up** button to bring the desired protocol to the top of the list.

Deleting a Scanning Protocol

You can delete unwanted scanning protocols.

▶ **To delete the default scanning protocol**

1. Touch the desired scanning protocol in the list at the left of the screen.
2. Touch **Remove**.
3. Confirm that you want to delete the protocol.

⚠ ***Note:*** *You can delete any scanning protocol except the Auto protocol.*

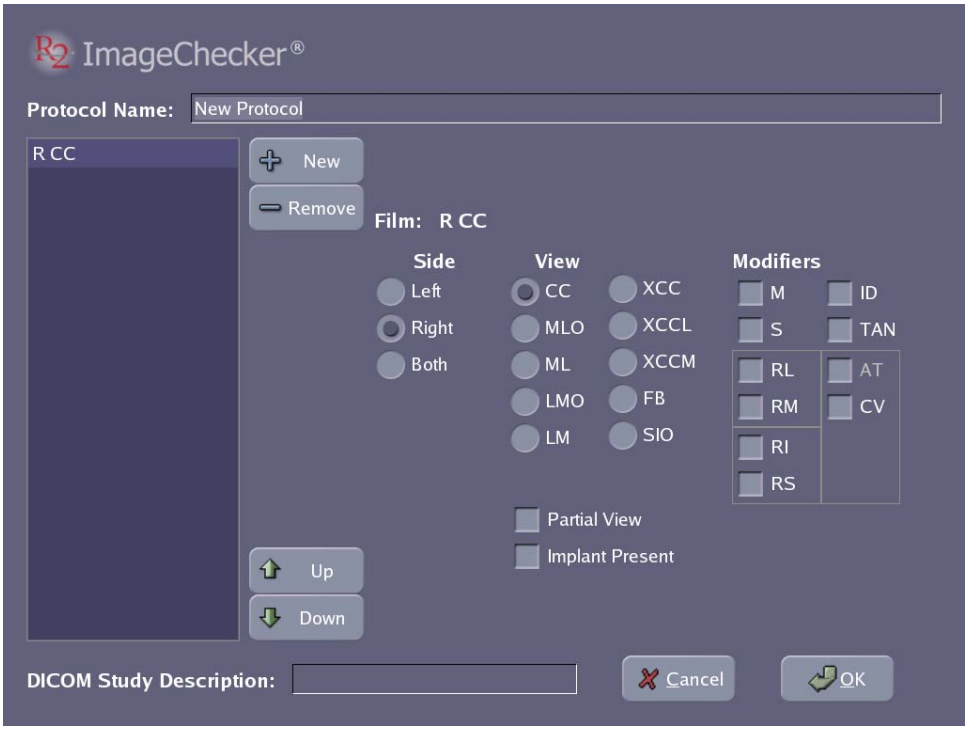
Creating Scanning Protocols

The Scanning option on the Controls screen allows you to create custom scanning protocols, and edit or delete existing protocols.

▶ **To create a new scanning protocol**

1 Touch **New** on the Controls Scanning screen to display the Edit Protocol Screen.

2 Touch (or click in) the Protocol Name field, and enter a name for your new protocol.



3 Touch **New** to add a film view to the protocol. Build the film view from left to right: select a side, a view, and any modifiers.

a Touch the proper Side selection: **Left**, **Right**, or **Both** (if cleavage view).

b Touch to select the View. Note the two additional selections below the view area for Partial View and Implant Present.

c Touch to select any modifiers needed.

⚠ ***Note:*** *As you build the film view, invalid selections are eliminated. For example if you choose Both for the side, the view is set to CC and the modifier is set to CV. Valid modifiers can be chained together as needed. Some modifiers (for example, M and S) are added before the view designation, other modifiers (such as ID and TAN) are added after. For a list of supported views see* *'CAD-Supported Views' on page 26.*

4 Repeat step **3** for each film view you wish to add to the scanning protocol.

- To move a view, touch a view name in the list at left and then touch **Up** or **Down**.
- To remove the view from the scanning protocol, touch a view name in the list at left and then touch **Remove**.
- To enter a study description, touch the **DICOM Study Description** field.

5 Touch **OK** when finished.

Editing Scanning Protocols

You can edit scanning protocols from the Controls Scanning screen.

▶ **To edit a scanning protocol**

1. Touch a scanning protocol in the list at the left of the screen.
2. Touch **Edit** to open the Edit Protocol screen.
3. Edit the Protocol. You have the following options:
   - To change the view order, touch a view name in the list at the left, then touch **Up** or **Down** as needed.
   - To remove the view from the scanning protocol, touch the view name, then touch **Remove**.
   - To enter a new name for the protocol, touch the Protocol name, then enter a new name.
   - To add a new view to the protocol, touch **New.** Build the view from left to right starting with the side, then a view, then modifiers.
   - To add or change the DICOM study description, touch the field and edit the study description as desired.
4. Touch **OK** when finished, or touch **Cancel** to cancel changes to the scanning protocol.

⚠ ***Note:*** *You can edit any scanning protocol except the Auto protocol. If you delete all views from a Manual protocol, the protocol will be equivalent to the Any protocol.*

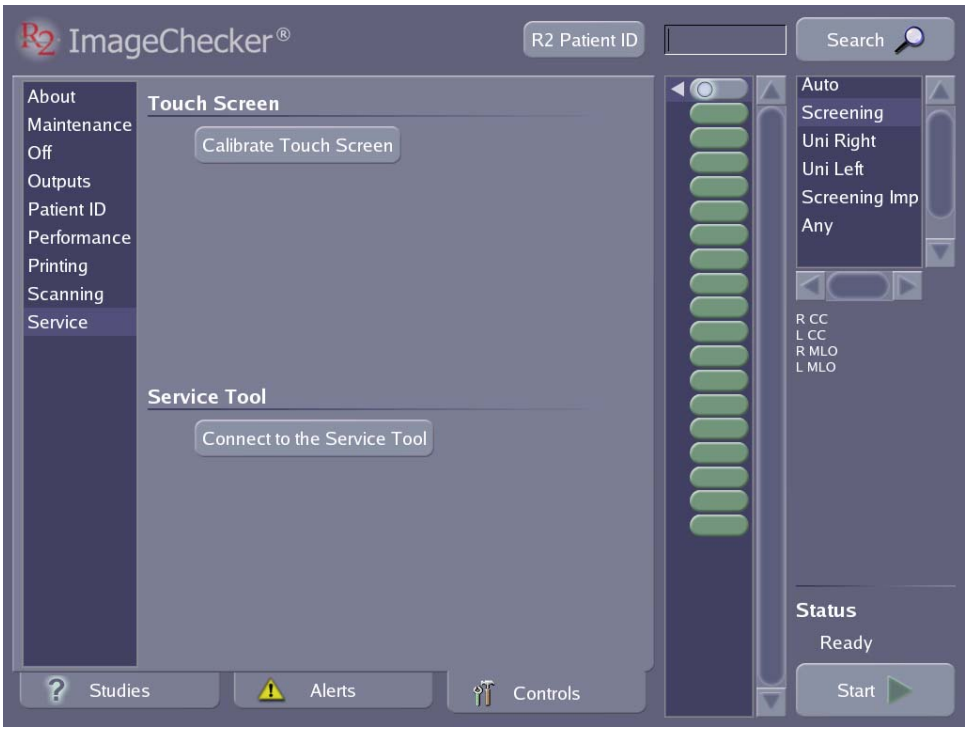
5.9. Service Utilities

The Service option on the Controls screen allows:

- Calibrating the touch screen
- Access to the service tools (for service personnel only)

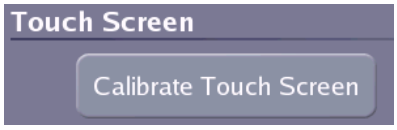
▶ **To display the Service screen**

Touch the **Controls** tab and then select **Service**.



Calibrating the Touch Screen

Calibrating the touch screen can make it easier to precisely touch the buttons and other controls.



To calibrate, first touch **Calibrate Touch Screen**, and then follow the simple on-screen instructions. When you finish, you will have to restart the system to save the new settings.

Connecting to the Service Tool

Access to the service tool is password protected and intended solely for use by authorized Hologic | R2 service personnel.

Part 6: Maintenance

- 6.1. Maintenance Reminders
- 6.2. Cleaning the Scanner
- 6.3. Power-Cycling the System
- 6.4. Running the Weekly Tests
- 6.5. Resetting the Handheld Barcode Scanner

Part 6 provides maintenance procedures that must be performed **weekly** to ensure optimal system performance. Hologic | R2 strongly recommends you follow all maintenance instructions given in this manual.

6.1. Maintenance Reminders

The system automatically issues a reminder message whenever a required maintenance procedure must be performed. The reminder messages are listed below.

Diagnostic tests failed

The scanner diagnostic tests failed. Each time the system starts up, the scanner performs tests to make sure all internal systems are working properly. You cannot scan until the scanner passes its tests. To fix the problem, power-cycle the system. See '6.3. Power-Cycling the System'. If this doesn't resolve the problem, call Hologic | R2 Technical Support.

Reminder: Please clean the scanner

Clean the scanner regularly in order to keep the system performing optimally. For instructions on cleaning the scanner, see '6.2. Cleaning the Scanner'.

Test Films: Needed

The system test films have not been run, are overdue, or have failed. To fix the problem, see '6.4. Running the Weekly Tests'. (More information about individual film tests is available on the Controls Performance page; see '5.6. Performance Options'.)

Preventive maintenance is required

Your system is due for its quarterly preventive maintenance servicing. Call Hologic | R2 Technical Support to schedule an appointment. In the meantime, you can continue scanning. If the system is not serviced within 180 days, the alert will appear continuously.

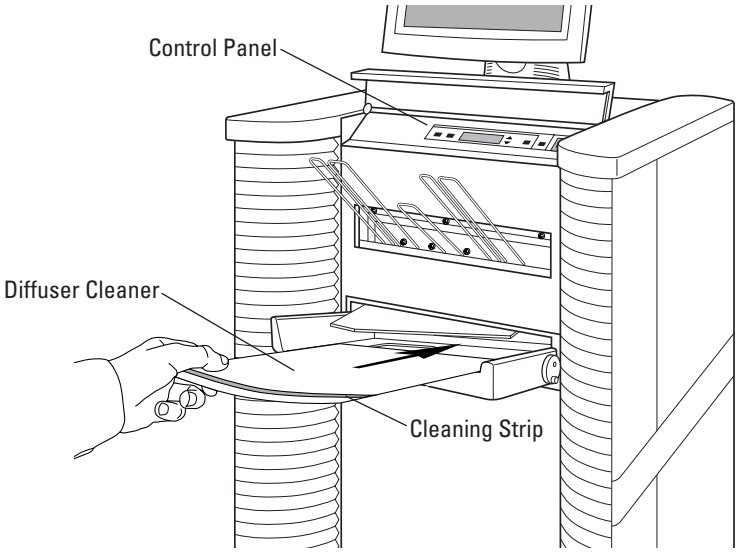
6.2. Cleaning the Scanner

To ensure optimum scanner performance, at least once each day clean the scanner diffuser, and then clean the scanner's suction cups using alcohol and the cleaning swabs provided with the system.

⚠ ***Note:*** *If you are running less than 80 cases daily, you can clean the scanner once each day. If you are running 80 or more cases daily, Hologic|R2 recommends that you clean the scanner twice each day.*

To clean the scanner diffuser

1 Place the diffuser cleaner in the input tray, with the cleaning strip facing up, closest to you.



Diffuser Cleaner

2 Lift the cover so you can see the scanner control panel.

3 On the scanner control panel:

- **a** Press QUIT.
- **b** Press MENU until '4 CLEANING MODE' appears on the scanner control panel display, and then press ENTER.
- **c** Press the UP/DOWN button until 'DIFFUSER CLEANING' appears on the display, and then press ENTER.
- **d** Press START/STOP. The scanner loads the diffuser cleaner.
- **e** When you see 'DIFFUSER CLEANING PULL OUT CLN_FILM' on the display, pull out the cleaner sheet, gently but firmly.

4 Repeat steps **1**–**3** two more times.

⚠ ***Note:*** *If an error occurs, run the diffuser cleaner through the system six times, and then shut down and restart the system.*

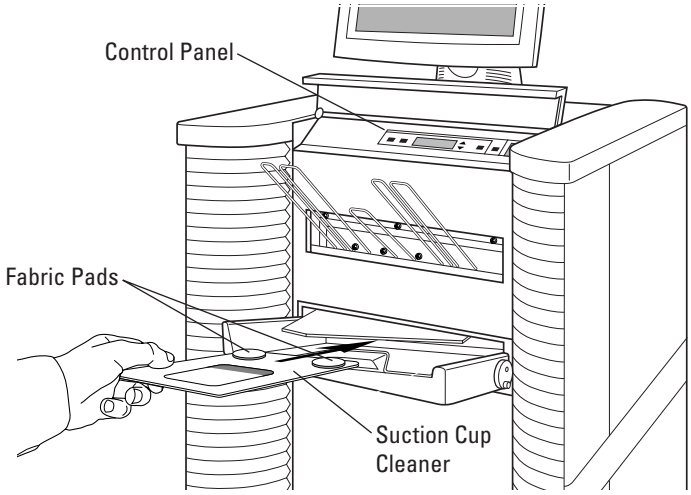
5 Store the diffuser cleaner in a safe, clean location.

▶ **To clean the suction cups**

1 Place about 5 drops of 70% isopropyl alcohol onto each pad of the suction cup cleaning plate, and rub it in gently with your finger.

⚠ ***Note:*** *Use isopropyl alcohol regardless of any instructions on the cleaning plate.*

2 Place the suction cup cleaner in the input tray, adjacent to the left side of the tray.



Suction Cup Cleaning Plate

3 Lift the cover so you can see the scanner control panel.

4 On the scanner control panel:

a Press QUIT.

b Press MENU until '4 CLEANING MODE' appears on the control panel display, and then press ENTER.

c 'SUCTION PAD CLEANING' appears on the display. Press ENTER to continue.

d When 'SET CLN_PLATE & PUSH <START/STOP>' appears on the display, press START/STOP.

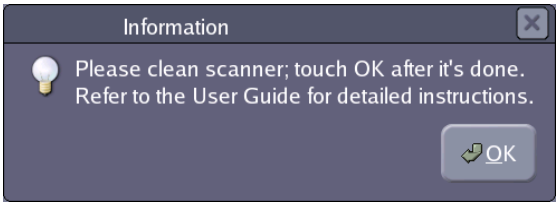
5 Repeat step **4** two more times.

6 Remove the suction cup cleaning plate from the tray and store it in a safe, clean location along with the diffuser cleaner.

⚠ ***Caution:*** *After cleaning the suction cups, wait at least five minutes before scanning any films. Residual alcohol can damage the films!*

7 After cleaning the suction cups, touch the **Controls** tab and then **Performance**.

8 Touch the **Clean Scanner** button. The system displays:



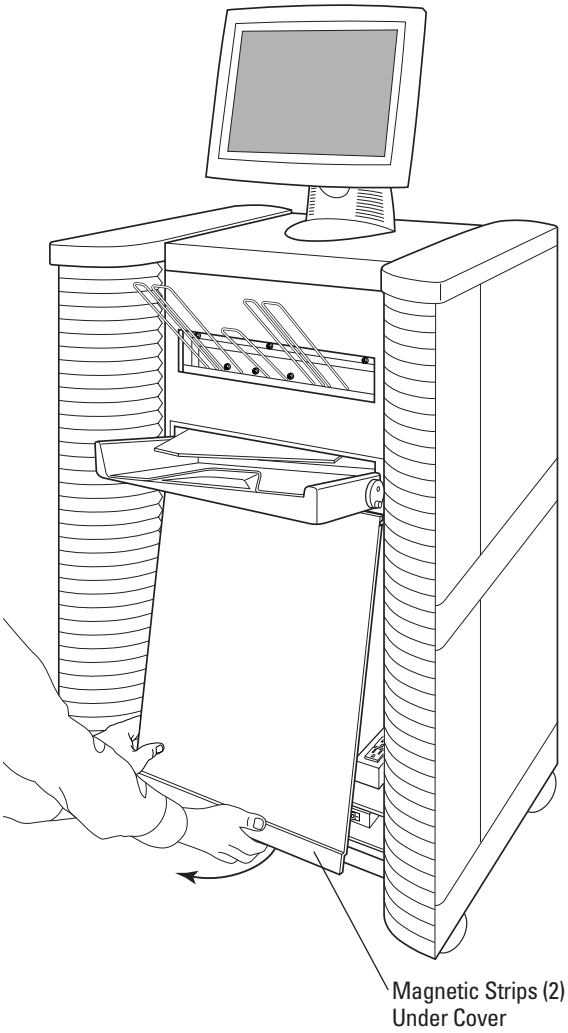
9 Touch **OK**. When you touch OK, the Scanner Cleaning message on the Maintenance screen changes from 'Needed' to 'OK'.

6.3. Power-Cycling the System

'Power-cycling' means to shut down the computer and then switch it back on. By power-cycling once a week, you will help keep the processing unit computer operating properly.

▶ **To power-cycle the system**

1. Touch the **Controls** tab and then select **Off**.
2. Touch the **Shutdown** button. After the software application shuts down, the monitor displays 'Power down…'
3. Release the front cover as shown below.

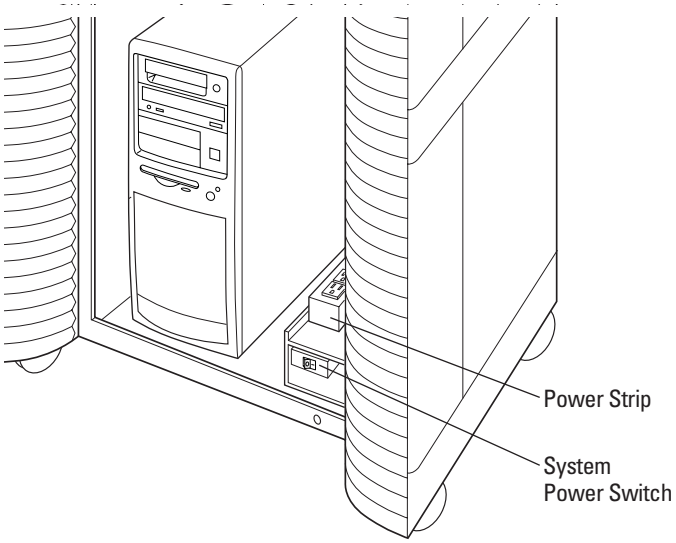


Front Cover Removal

⚠ ***WARNING!*** *In the next step, be careful when lifting the cover; it's heavy.*

4. Lift the cover up to free its top lip from the frame on which it hangs, and then set it aside.

5 Switch off the system using the power switch beneath the power strip.



Shutting Off the System

6 Wait ten (10) seconds. Switch on the system using the power switch. When the Studies screen appears, the system will be ready for use.

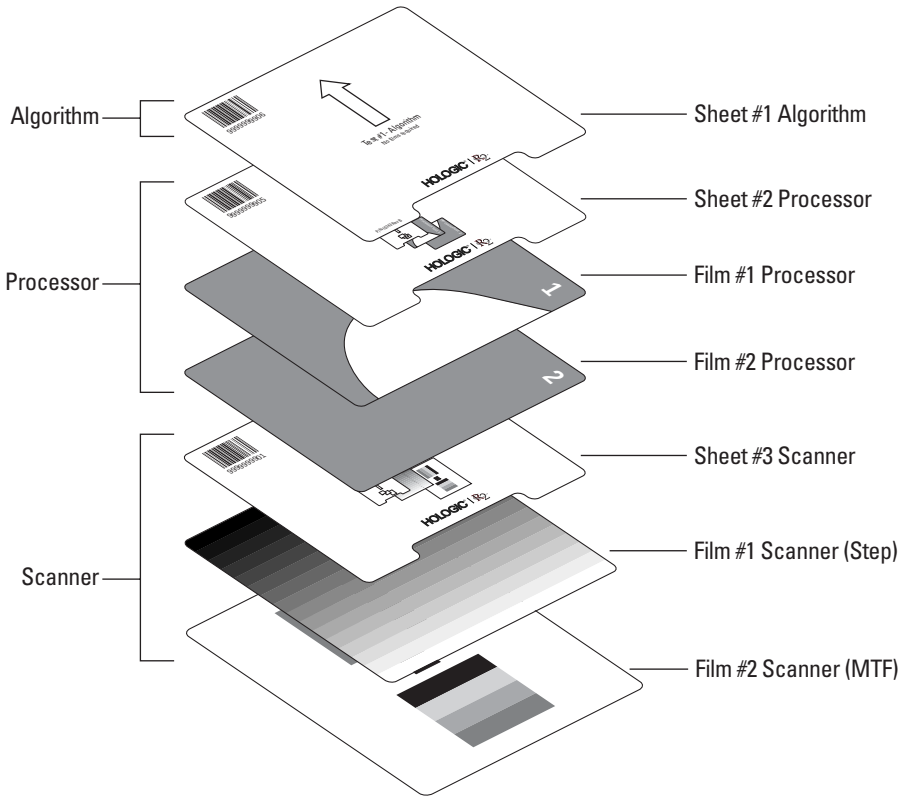
6.4. Running the Weekly Tests

Three tests must be run weekly to ensure optimal system performance. Always run the tests together and in this order: Algorithm on top, then Processor, then Scanner – think 'APS'!

▶ **To run the weekly tests**

1 Stack the test sheets and films as shown. Note that the test films are ordered as if they were ordinary films.

⚠ ***Important!*** *If your system does not have the CAD license, do not run the Algorithm and Processor tests. Run only the Scanner test films.*



2 Place the stack in the input tray and touch **Start**. The computer recognizes the test film barcode numbers and automatically changes to Test mode. The test requires about five minutes to complete.

3 When done, review the results by touching the **Controls** tab and then selecting the **Performance** option.

4 Verify that all test results read 'PASSED'.

- If all tests pass, you're done for the week.
- If any test reads FAILED, rerun ALL the tests. Be sure that the test sheets and films are loaded in the correct order. If any test fails again, power-cycle the system (see '6.3. Power-Cycling the System') and rerun all the tests.
- If any test fails again, call your Hologic | R2 service representative.

6.5. Resetting the Handheld Barcode Scanner

Occasionally it is necessary to reset the handheld barcode scanner software to its default settings. If the barcode scanner stops reading barcodes properly, use the barcode labels provided in this section to reset it.

▶ **To reset the handheld barcode scanner**

1. Scan the 'Enter/Exit Configuration Mode' barcode shown below. When you scan the barcode, the scanner should beep three times.

Enter/Exit Configuration Mode

2. Scan the 'Recall Defaults' barcode. When you scan the barcode, the scanner should beep once. This erases all previous settings and returns the barcode scanner to its factory default communications settings.

Recall Defaults

Part 7: Using DigitalNow and the R2 Patient ID System

- 7.1. Overview
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Part 7 provides information about DigitalNow, which provides archiving features and the R2 Patient ID system.

7.1. Overview

The R2 DM system supports the archiving of digitized film images and CAD results for supported DICOM views. You can enable and disable the archiving features by means of the Outputs option on the Controls screen. At the time of installation, the features are set either to On or Off, based on your preference.

The Archiving feature requires a patient information database from which to draw the necessary patient information. This ensures that the images and CAD results are stored properly in the archive. Therefore, the Patient ID feature must be enabled and the system configured to communicate with a reporting system (e.g., R2 Technology Patient ID, MagView, MRS, or PenRad) in order for the Archiving feature to function. In addition, the R2 system must be configured to communicate with the archive system.

If both Patient ID and Archiving are enabled, the images and any CAD results are sent to the archive system after the images are processed.

These archived images and CAD results, like any other record in the archive system, can then be retrieved and viewed on softcopy review workstations and/or printed.

7.2. DigitalNow Archiving

The workflow for DigitalNow archiving is as follows:

1. At any point prior to scanning film mammograms for a case, you must enter the R2 barcode on the separator sheet used for the case into the record for the appropriate patient in the patient information database.
2. Then, the films can be scanned. The system retrieves the patient information from the patient database, and transfers the images and CAD results to the archive system. The images and CAD results are also sent to the display units to which the R2 system is configured to send.

   If images are scanned with a Manual protocol, and archiving is set to 'On with verification', you must verify the images are correct before they can be sent to the archive. For more information, see '3.9. Verifying Scanned Cases'.

   Once the images and CAD results are stored in the archive, they can be manipulated like any other record in the archive system. You can send them to the softcopy digital review workstation or printer. Keep in mind that once film mammograms are digitized and archived, they are treated like digital images and will not be sent to display units other than a softcopy digital review workstation or printer.

   If archiving is enabled, and no record in the patient database matches the R2 Technology barcode, the system does not process the case. You can correct this by entering patient information in the database after the case is scanned and reprocessing the case.

7.3. Using the R2 Patient ID System

For sites that do not have a patient database but want to use DigitalNow, Hologic | R2 provides the R2 Patient ID system.

The purpose of this patient identification database is to enter the patient information necessary to archive images and/or CAD results. You cannot query the database, view or manipulate records. The information remains in the database for only 96 hours (four days) from time of entry.

The R2 Patient ID system can be used in conjunction with the DICOM Modality Worklist, Study Root , or Patient Root Queries (as described in 'Querying an External Database' on page 95) to retrieve information from your Modality Worklist or PACS.

To enter patient information, your service representative must have configured your system to use the R2 Patient ID system. In addition, reporting system connectivity must be enabled by a service engineer.

You need the following information:

- Database password: h0spital (the second character is a zero, not the letter 'O')
- IP address for the R2 DM system

Once you have this information you can enter patient information.

⚠ ***Note:*** *For sites with multiple film-scanning units: When you access the Patient ID database, make sure you access the R2 system that you will be using to scan the studies. Each system maintains its own database – you must enter the patient information into the database of the R2 system on which you plan to scan the images. Each film-scanning unit can be given a unique name during installation, and this name is displayed in the R2 Patient ID web page.*

▶ To enter patient information

1. Touch the **R2 Patient ID** button at the top of the screen to access the Patient ID system directly from the system.

   OR

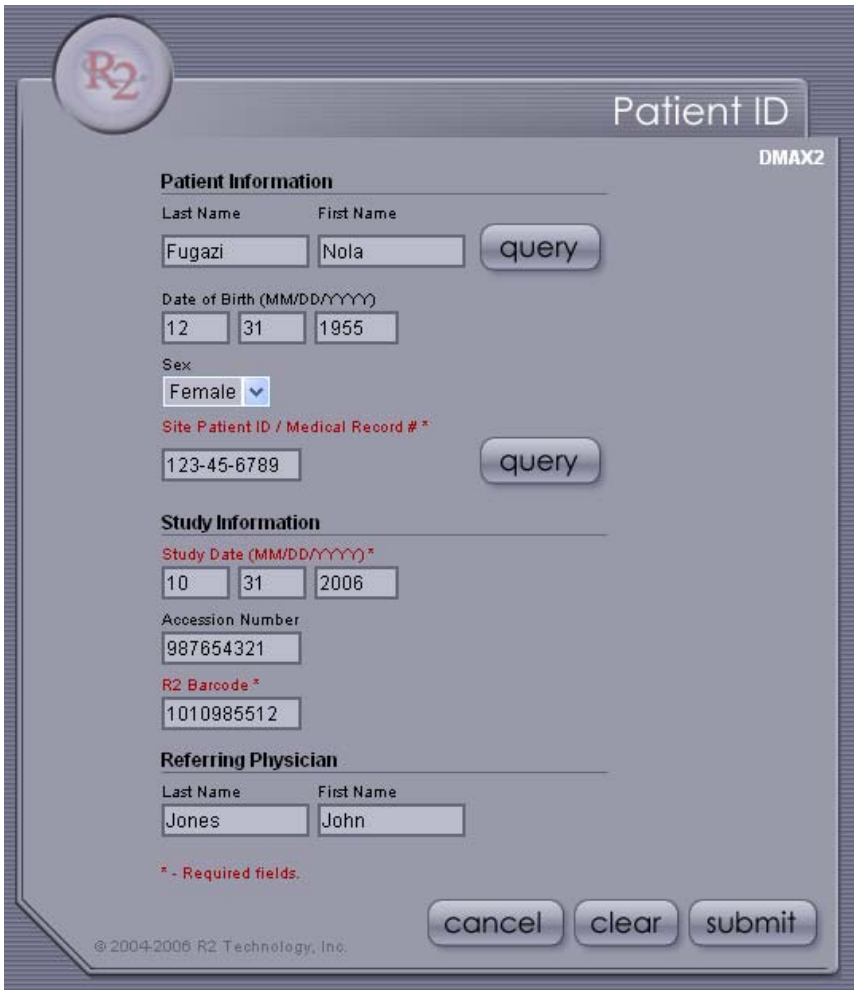
   To access the Patient ID system from any computer on the same network as the R2 system, using any web browser, type the IP address for the processing unit followed by /id in the Address box, and press ↵Enter. For example:

   http://12.345.67.89/id

   The browser will display the log-in window.

2. Enter your Patient ID database password (h0spital), and click **login**.

The system displays the patient information entry page:



⚠ ***Note:*** *The **query** buttons appear on this screen only if they were configured to appear by the Hologic|R2 service engineer when the system was installed.*

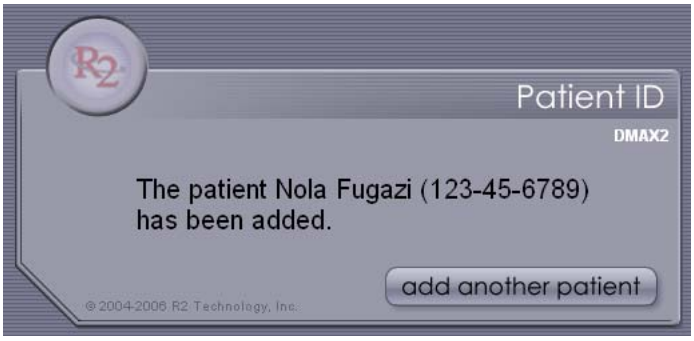
3 Enter the patient information, Study Date, and R2 barcode number. Required fields are marked with an asterisk (*).

- Enter the patient information either by typing it in, or by querying a PACS/ workstation (as described under 'Querying an External Database' on page 95).
- Enter the R2 barcode number into the 'Accession Number' field by either scanning the barcode on the separator sheet, or typing it in.
- Enter the correct Study Date. (The Study Date defaults to the current date.)

⚠ ***Note:*** *Some reporting systems generate a Study Instance UID (unique ID) that is used to identify a given study. If you query to retrieve patient information and then enter new information (or change the information), then the R2 system generates a new Study Instance UID that it will send to the PACS with the study results.*

⚠ ***Note:*** *When you query a PenRad system, it will not return a study date. Instead, the R2 system assigns the current (today's) date. If a different date is needed, you will need to enter the information manually in the Study Date field.*

4 Click **submit**. The system confirms that you have added the patient.



You will not be able to verify that the information you enter is correct. If you believe you made a mistake, enter the information again. If an identical record is entered, it will simply overwrite the previous one.

Once you have submitted the patient information and R2 barcode, you can scan the case.

⚠ ***Important!*** *Be careful when entering the information. This is the mechanism that links the images to the correct patient. When viewing digitized images from an archive, always check the patient flash to ensure the case corresponds to the desired patient.*

To enter multiple studies from different dates for the same patient, you will need to enter the studies separately using the R2 barcode from the separator sheet for each study.

Querying an External Database

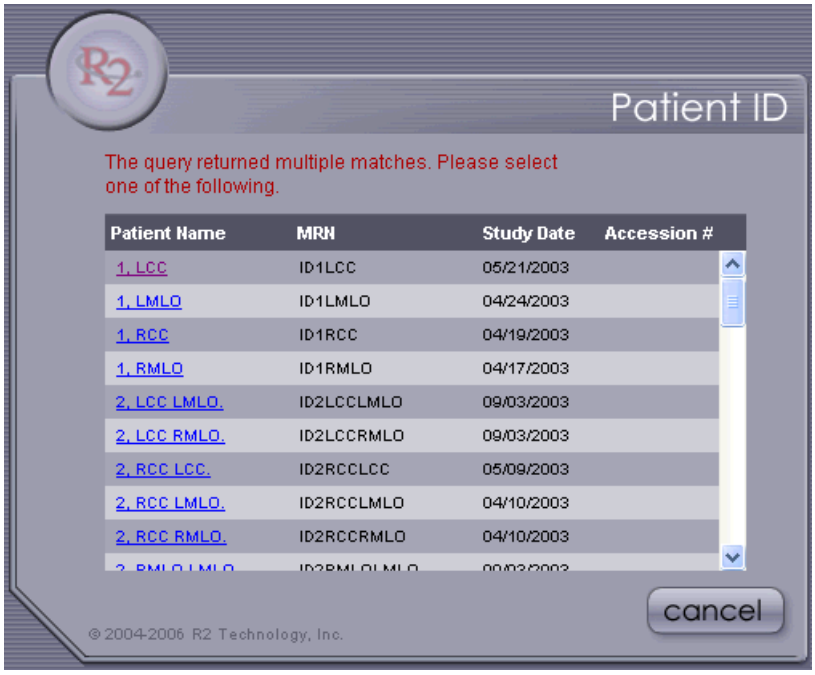
You can enter patient information onto the patient information entry page by querying a PACS/workstation (configured by the Hologic | R2 service engineer when the system was installed).

There are three types of queries; the type you can run was configured by the Hologic | R2 service engineer. The following types are available:

- **DICOM Patient Root Query**. If this was configured, only the **query** buttons in the Patient Information section of the patient information entry page are active. When you query by touching the **query** button to the right of the patient name fields, the system queries using only those fields. When you query by touching the **query** button to the right of 'Site Patient ID / Medical Record #' field, the system queries using only that field. With either button, the query result returns data for just the fields in the Patient Information section.
- **DICOM Study Root Query**. If this was configured, only the **query** button in the Study Information section of the patient information entry page is active. When you query by touching the **query** button to the right of the 'Accession Number' field, the system queries using only that field. The query returns data for all fields on the page.
- **DICOM Modality Worklist Query.** If this was configured, all three **query** buttons are active. When you query by touching any **query** button, the system queries using only the field(s) to its left. The query result returns data for all fields on the page; however, the data entered into 'Study Date (MM/DD/YYYY)' comes from the Scheduled Procedure Step Start Date field in the database.

⚠ ***Note:*** *These queries do not enter the R2 barcode number. You'll need to enter it as described in step 3 in the preceding procedure.*

If you leave the field used by the query blank, the query will return a list of all studies in the database. If you enter into the field one or more characters that appear in the data you want to match, the system will return a list of just the studies containing the matching data.



To select a study and copy its data onto the patient information entry page, touch its entry in the Patient Name column.

7.4. Assigning R2 Barcodes in Other Databases

The R2 Patient ID feature supports most mammography reporting systems. This section explains how to enter the R2 barcode from the separator sheet into the record for the patient.

⚠ ***Note:*** *Many reporting system vendors are now supporting DICOM Modality Worklist Query, which has become the standard method for interfacing with reporting systems. Users should consult their reporting system vendor for information about software upgrades that include support for DICOM Modality Worklist Query.*

Assigning a Barcode in PenRad

You can assign up to three barcodes to each patient record. You must enter the barcode in the patient record before you run the films through the R2 system.

▶ **To assign a barcode in PenRad**

1. Log into PenRad and go to the Breast Imaging Main screen.
2. Use the barcode scanner to scan the R2 barcode on the separator sheet that you will be using to scan the films on the R2 system. The barcode number is automatically entered into the patient record.

   Or, type in the barcode(s).

Assigning a Barcode in MagView

With MagView systems, the R2 barcode is used as the Patient ID.

Whether you are adding a new patient or scanning a case for a patient that already exists in the system, enter the R2 barcode as the Patient ID or Medical Record Number.

Before scanning the studies, access the record for the existing patient (or add a record in the case of a new patient). For the Patient ID or Medical Record number, enter the R2 barcode.

At that point, you can scan the case(s).

Assigning a Barcode in MRS

After you add or open a mammogram in MRS, scan the R2 barcode from the separator sheet into the Unique Exam Number field, and then save it as either 'On Hold' or 'Waiting for Findings'.

The R2 barcode identifies up to twenty four film views per study.

⚠ ***Note:*** *The R2 barcodes are unique; however, they are eventually recycled by the system.*

When the films are ready to be scanned, the R2 system queries the MRS database using an SQL stored procedure. The query uses the R2 ID passed prior to the film digitization as its key for data retrieval. The fields extracted from the MRS database by the R2 system include the Patient Last Name, Patient First Name, Patient ID, Date of Birth, Sex, Referring Physician Last Name, Referring Physician First Name, Accession # (always a zero), and Procedure Date.

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